

# Infant Bacterial Therapeutics AB

Annual Report 2020



## **We aim to satisfy unmet medical needs in the premature infant**

### *SIGNIFICANT EVENTS 2020*

The COVID-19 pandemic affects our development work, for example, activation of hospitals (trials), which has not occurred at the desired rate. As of the date of this annual report, approximately half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study currently does not take place at the desired rate.

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IBT's application for clinical trial was approved in Israel in January, in Poland in October and Bulgaria in November.

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# **Infant Bacterial Therapeutics AB (publ)**

## **Annual Report** January 1 – December 31, 2020

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## *IBT IN BRIEF*

*IBT is a pharmaceutical company with its registered office in Stockholm with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. IBT is currently developing its lead drug candidate IBP-9414, to prevent NEC and improve feeding tolerance in premature infants. IBP-9414 contains the active compound Lactobacillus reuteri, which is a human bacterial strain naturally present in breast milk. IBT is further pursuing a second rare disease program IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in infants. By developing these drugs, IBT has the potential to fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.*

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### *Vision*

Premature infants are the most vulnerable beings on the planet and for them to survive, grow and thrive they need intensive and specialized care. Although advances in medical care and handling over the last 30 years have improved survival and well-being of these sensitive infants, both in the immediate post-natal period and in their subsequent lives, current drugs and therapies are mostly designed for adults and are not adapted to this specific and vulnerable patient population. Specific treatment and prophylactic therapy are thus underdeveloped and there is an urgent demand for drugs designed for the unique needs of the premature baby.

IBT has a vision to become an internationally recognized and leading company in the development of therapies to prevent or treat diseases of the premature infants.

### *Mission*

IBT develops, and intends to market and sell safe and efficacious therapies well adapted to its purpose that affects infants' microbiome and thereby prevent or treat rare diseases that affects premature infants. IBT seeks to remain close to the needs expressed by healthcare providers and parents to provide satisfactory therapeutic solutions and continuously improve these solutions.

### *Partners*

Clinical trials are conducted through collaborations with CRO's or leading academic research groups chosen based on their experience and specialist knowledge in conducting clinical trials. Suitable sites are selected in cooperation with IBT to conduct clinical trials and to initiate the recruiting process for patients. IBT can monitor the clinical operations and pharmaceutical safety internally, or delegate these activities to the chosen CRO.

## IBT's history

### 2013

- ▶ IBT is founded as a subsidiary to BioGaia and commences the development of a preventive therapy (IBP-9414) against NEC using *Lactobacillus reuteri*
- ▶ IBT is granted Orphan Drug Designation by the FDA for *Lactobacillus reuteri* for the prevention of NEC in premature infants
- ▶ FDA provides scientific input to IBT development plans

### 2014

- ▶ Pharmaceutical development defining the manufacturing process of IBP-9414
- ▶ EMA provides scientific input to IBT development plans

### 2015

- ▶ IBT is granted Orphan Drug Designation by the European Commission for IBP-9414 including *Lactobacillus reuteri* for the prevention of NEC in premature infants
- ▶ Production of drug candidate IBP-9414 according to all applicable pharmaceutical chemistry-manufacture-control regulations for the safety and tolerability study
- ▶ Active IND obtained from FDA for start of Safety and Tolerability clinical trial in 2016
- ▶ IBT received approval from the MPA to conduct a clinical trial in Sweden

### 2016

- ▶ Separation of IBT from BioGaia
- ▶ Listing on Nasdaq First North
- ▶ IBT receives Rare Pediatric Disease Designation from FDA for IBP-9414
- ▶ IBT adds new indication for Gastroschisis IBP-1016

### 2017

- ▶ IBT's share of series B is traded on First North Premier
- ▶ IBT completes IBP-9414 safety and tolerability trial and announces that top line data demonstrate similar safety and tolerability profile in the active and placebo groups
- ▶ EMA adopts a positive opinion on the Pediatric Investigational Plan proposed by IBT for the development of IBP-9414 for the prevention of NEC

### 2018

- ▶ The EGM on January 8 decided on a new share issue amounting to SEK 439.1m and as of January 31 the share issue was fully subscribed. The share issue in combination with

the directed share issue in November of 2017 generated approximately SEK 543.6m prior to transaction costs

- ▶ In June 2018, IBT contracted Premier Research International LLC, the company's CRO during the Phase II clinical trial, to also conduct the company's Phase III clinical trial
- ▶ IBT series B shares are traded on Nasdaq Stockholm, Mid Cap
- ▶ IBT has, resulting from discussions with the FDA chosen to modify its Phase III study for the prevention of necrotizing enterocolitis (NEC) in premature infants. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as improvement of "feeding tolerance", that could increase the chance of success in the Company's Phase III study and the market potential of the product

## 2019

- ▶ IBT signed its first distribution agreement on March 5, 2019, for its product IBP-9414, with MegaPharm Ltd. for the Israeli market and the Palestinian Authority's territories
- ▶ On May 19, 2019, it was announced that IBT had responded satisfactorily to the comments that the FDA had regarding the study design to the companies planned Phase III Study which led to the approval of IBT's IND (Investigational New Drug) application. As a consequence of the FDA's comments, an evaluation of the effects of IBP-9414 on the digestive system, or so called "feeding tolerance" of premature infants in the ongoing Phase III study is now included
- ▶ During 2019 IBT's application for clinical trial was also approved in the UK, France, Hungary and Spain
- ▶ IBT announced on July 4, 2019 that the first patient had been recruited in the company's pivotal clinical Phase III study, The Connection Study

## 2020

- ▶ The COVID-19 pandemic affects our development work, for example, activation of hospitals, which has not occurred at the desired rate. As of the date of this annual report, more than half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study currently does not take place at the desired rate
- ▶ IBT's clinical study application was approved in Israel in January, in Poland in October and in Bulgaria in November

## MESSAGE FROM THE CEO

### **Significant medical need**

We are presently conducting a Phase III study (“The Connection study”), i.e. the final phase in our development program with the drug candidate IBP-9414 containing *Lactobacillus reuteri* as the active substance, a natural strain of bacteria present in human breast milk. The study objective is to demonstrate that IBP-9414 can prevent NEC and improve “sustained feeding tolerance”. First a few words regarding the importance of feeding the premature infant.

At birth, the umbilical cord is severed, and thereby so is the induction of nutrition to the newborn baby. In the mother’s womb the baby doubles its weight every three to four weeks towards the end of a normal pregnancy. One major challenge for medical staff caring for premature infants is that these infants must receive a significant amount of nutrition to grow and develop. Medical staff seek to provide the best possible environment to ensure that the premature infants in the neonatal wards have the greatest opportunity to grow and develop in a similar way as if the infant had remained in the mother’s womb.

Infants can receive nutrition in two ways; enteral and parenteral, i.e. by eating or intravenously. One complicating factor with premature birth is that the digestive system is burdened with food earlier (at around gestational week 25) compared to the time of initial feeding in a normal term birth (at gestational week 40). The gastrointestinal system in the premature infant has not developed sufficiently to absorb the food which may cause impaired uptake of nutrition as well as serious complications such as the serious disease NEC. In addition, it is well documented that use of parenteral nutrition at length can cause serious complications for the infant, e.g. sepsis. It is furthermore ascertained that malnutrition early in life may increase the risk for impaired cognitive function at school-age.

The medical need of well-functioning digestion is very significant in premature infants and our hopes are that IBT’s drug candidate IBP-9414 may improve the bowel function in nutritional uptake, and also to simultaneously minimize risks of several serious complications, such as NEC.

### **The recruitment rate for the Phase III study, “The Connection study”, and the impact of COVID-19 on the study**

The COVID-19 pandemic which has now lasted more than one year affects our Phase III study. In the beginning of 2020, before the pandemic, we concluded that the recruitment rate in The Connection Study was as expected, i.e. the study recruited the same number of patients per site and per month as we had in IBT’s Phase II study conducted at 15 hospitals in the USA in 2016-2017. Later during the spring our work encountered difficulties as we had to adapt to the COVID-situation. In the early fall of

2020 it appeared that the pandemic was under control, however the subsequent waves of COVID later in the year continued to affect us. IBT continues to activate new hospitals for participation in the study in spite of the pandemic, and currently in April, several hospitals are prepared to recruit patients, but are restrained by resources required to conduct the study being diverted within the hospitals for other activities, such as extensive vaccination programs. To date, clinical trial applications for “The Connection Study” are approved in the USA, Hungary, Spain, France, the UK, Israel, Poland and Bulgaria.

The initial phase (300 patients) of “The Connection Study” was concluded in February 2021. IBT hopes that diminishing effects of the pandemic combined with opening the study for infants with birth weight under 750 grams will significantly increase the recruitment level in 2021.

The pandemic affects our recruitment level, however not the quality of the data generated by the study. The bulk of the costs for conducting the study are generated in connection with recruitment of patients, and thus our assessment is that IBT has sufficient funds to conclude the study.

### **Important work during 2020**

During 2020 we strived to gain greater understanding of the value of our second primary “endpoint” in the Phase III study, “sustained feeding tolerance”. Post consultation with the FDA, we have established a group of experts comprising doctors, nurses and patient organizations. Our goal with the group of experts is to gain improved understanding and to demonstrate the impact of malnutrition in premature infants in both the short- and long-term. Work conducted by experts has already demonstrated that impaired feeding reduces growth in infants thereby causing significant suffering in combination with high costs for those who bear the costs of medical treatment. Additional work is required to quantify the market value of improved “feeding tolerance” for our product IBP-9414.

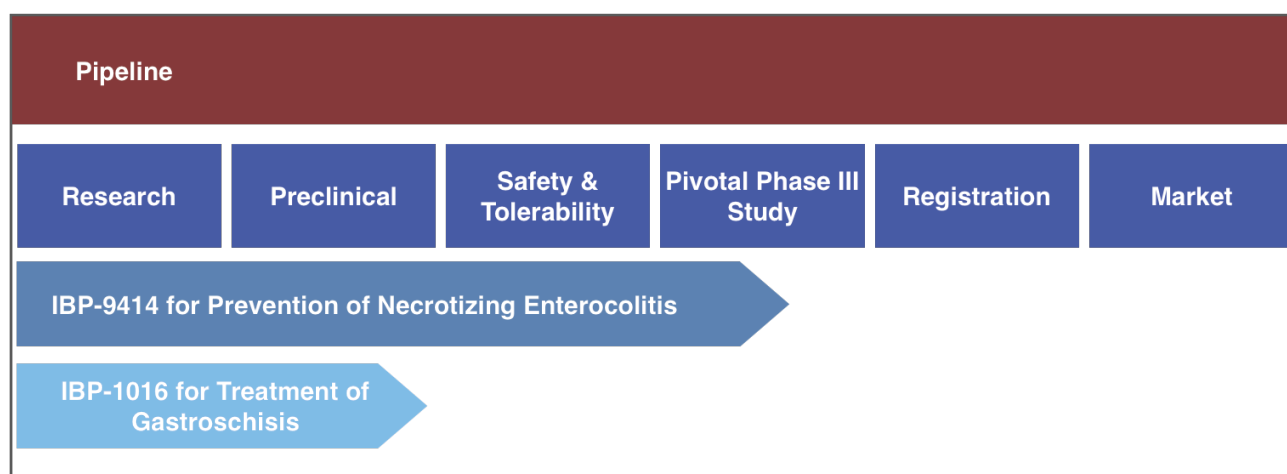
Additional clinical trial material was produced for the study in 2020, and it was determined that we have a scalable production method to be able to meet estimated future sales volumes. The product has also demonstrated in the conducted stability tests very good stability of up to four years.

IBT’s first own patent had been granted approval in Japan. This improves our patent protection and thereby IBT’s ability to safeguard its invention for a long time. In conclusion, I would like to take this opportunity to thank all employees who, with great commitment, drive work forward with a product that can play a major role for premature infants.

Stockholm April 8, 2021  
Staffan Strömberg  
CEO



## IBT's PIPELINE



### IBP-9414

IBP-9414 contains the active substance *Lactobacillus reuteri*, which is a co-evolved human bacterial strain naturally present in breast milk. *Lactobacillus reuteri* is a live bacteria known to be anti-inflammatory, anti-pathogenic and beneficial to gut motility. IBP-9414 is specifically formulated with the consideration of the extremely sensitive target population of premature infants.

IBT was granted Orphan Drug Designation by the FDA for *Lactobacillus reuteri* for the prevention of NEC in premature infants in 2013 and by the European Commission in 2015. IBT also received Rare Pediatric Disease Designation from the FDA for IBP-9414 in 2016, meaning that IBT may be awarded a priority review voucher following market approval.

In June 2016, IBT commenced a Safety and Tolerability study. At the end of 2017 the completed study results demonstrated a similar safety and tolerability profile both in the active group and placebo group.

IBT has, resulting from discussions with the FDA on November 20, 2018, chosen to modify its Phase III study in premature infants. Following the guidance from the FDA, IBT amended the protocol to allow additional claims such as improvement of “feeding tolerance”, that could increase the chance of success in the Company’s Phase III study and the market potential of the product.

The pivotal Phase III study, The Connection study, commenced in 2019 and the first patient was recruited on July 4, 2019.

## NEC

NEC is a leading cause of death among premature infants in neonatal intensive care units (NICU). NEC annually kills approximately 3,700 and 1,500 infants in Europe and in the US, respectively. NEC has an unpredictable, spontaneous, and acute onset and major surgery is today the only available treatment. NEC is a serious inflammatory disease of the newborn bowel in which portions of the bowel undergo tissue death (necrosis).

NEC primarily affects premature infants and the risk to contrive NEC increases the lower the birth weight and lower gestational age. Gestational age is defined as the duration from the first day of the last menstruation cycle until birth.

Occurrence of NEC by estimated gestational age is as set forth in Figure 1.

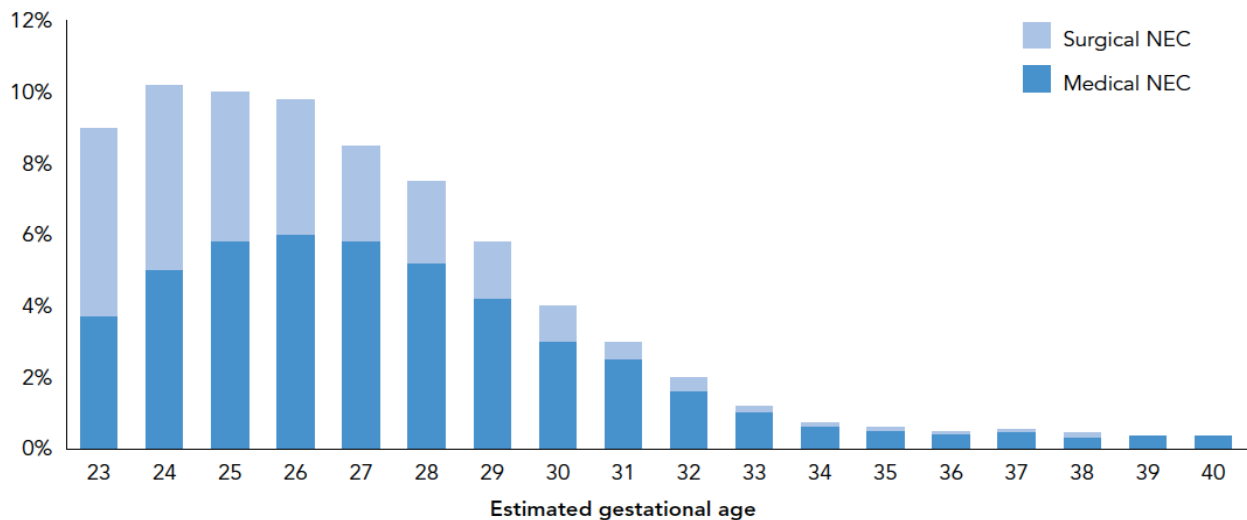


Figure 1. Occurrence of NEC by gestational age (Clark et al, 2012)

The disease has a higher rate of mortality in the younger and less mature infants. Mortality in infants who had a diagnosis of NEC by estimated gestational age is as set forth in Figure 2.

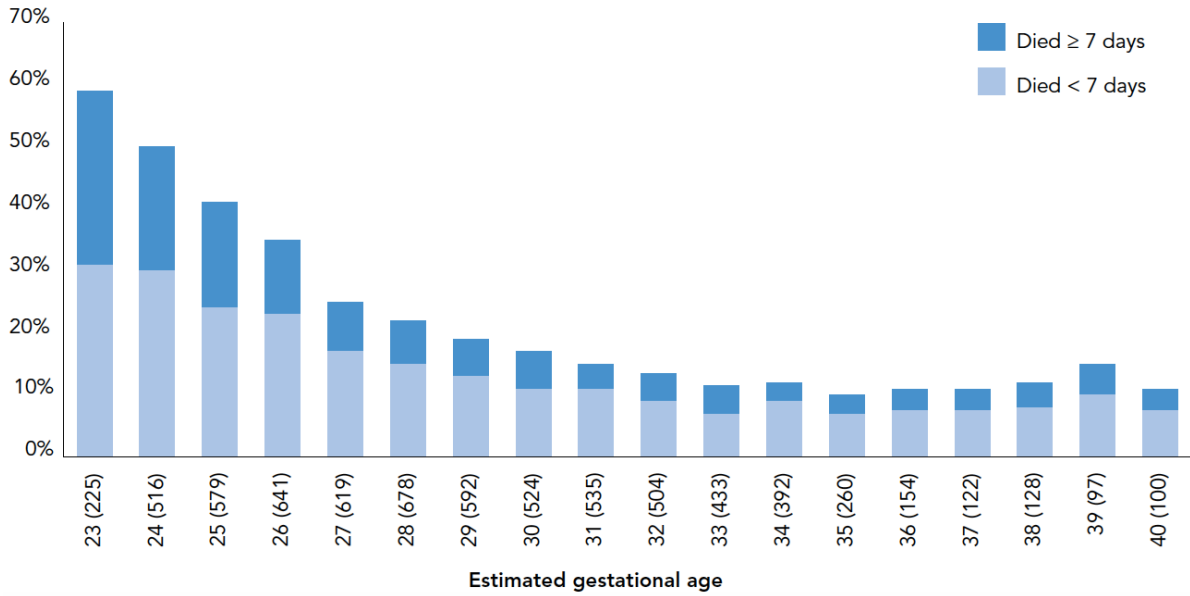


Figure 2. Mortality in infants who had a diagnosis of NEC by estimated gestational age (Clark et al, 2012). The number listed outside parentheses in the table above is estimated gestational age in weeks. The number listed within parentheses represents the number of patients with NEC within each gestational age group.

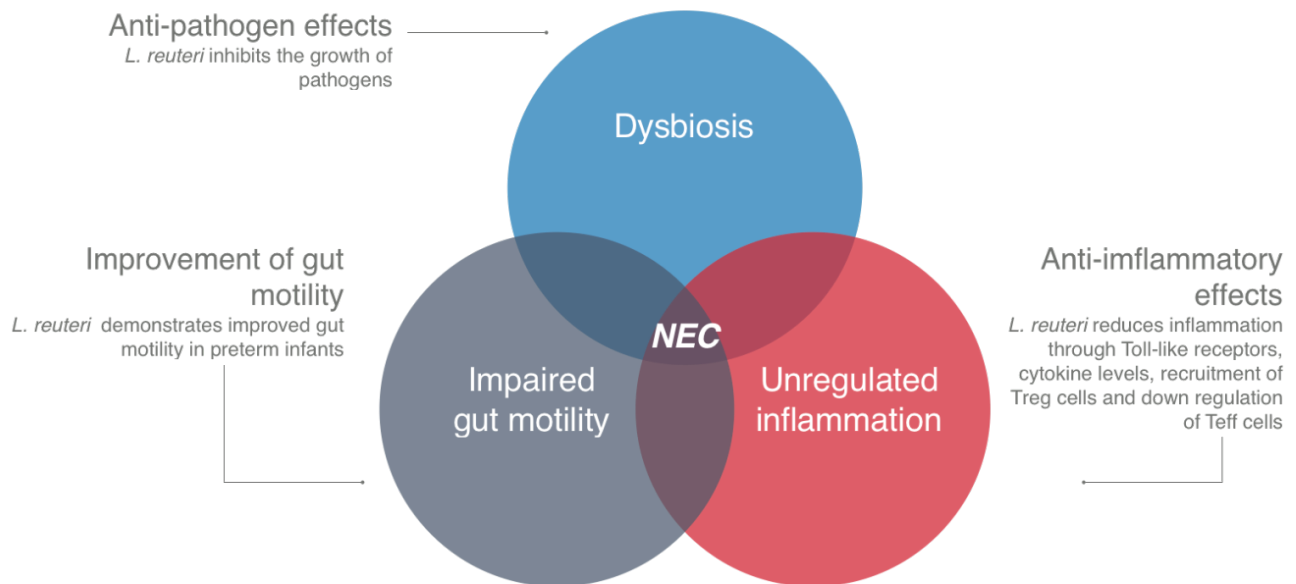
The long-term clinical consequences for infants who survive NEC are variable and include short bowel syndrome, parenteral nutrition-associated cholestasis, abnormal growth, and adverse neurodevelopmental outcomes, including cerebral palsy, cognitive impairment, visual impairment, and hearing impairment.

## *L. reuteri*

*Lactobacillus reuteri* is a co-evolved human bacterial strain naturally present in breast milk. *L. reuteri* is a live bacteria known to be anti-inflammatory, anti-pathogenic and beneficial to gut motility.

### Mechanism of Actions

*L. reuteri* has strain specific attributes that are relevant for NEC



## Feeding tolerance

The first weeks of nutrition have important implications for the development of preterm infants. The goal of achieving early and adequate enteral nutrition (tube feeding) in these infants is to facilitate recovery or catch up growth, to achieve normal body composition, whilst minimizing undesirable effects of nutritional imbalances (e.g. hyperglycemia, insulin resistance, etc.). Evidence-based guidelines for nutrition of VLBW-infants (infants with a birthweight of under 1,500 grams) recommend starting parenteral nutrition (intravenous) within the first hours postnatally as the immature gastrointestinal tract is not ready to accept full enteral feedings in these infants directly after birth. However, prolonged parenteral nutrition is associated with complications (intrahepatic cholestasis, increased risk of bronchopulmonary dysplasia, worsening of pulmonary vascular resistance, IV line-mediated infections and sepsis).

The enteral route of nutrition is the most physiological and natural way of administering nutrients to the neonate. The introduction of enteral feeding is therefore recommended as soon as possible, and ideally on day 1 with the goal of reaching full enteral nutrition

as quickly as possible. This eliminates the need for parenteral nutrition and the associated risks of complications. Establishing sustained enteral feeding, associated with the discontinuation of parenteral nutrition is thus an important goal, especially in VLBW and ELBW-infants (extremely low birth weight <1000g). Reducing the number of days to reach complete enteral nutrition is considered to be clinically relevant and important in the treatment of the preterm infant.

### Clinical Experience

Since 2012, thirteen published clinical trials that have enrolled more than 4,000 infants have indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* in the prevention of NEC.

Since 2012, nine published clinical studies that have enrolled more than 3,100 infants have indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* for the reduction in episodes of feeding intolerance or reduction in time to full enteral feeding.

The table below shows a summary of studies using *Lactobacillus reuteri* showing clear clinical signal for the reduction in NEC incidence and clear clinical signal for reduction in episodes of feeding intolerance or reduction in time to full enteral feeding.

NICU Study	Number of Patients	Reduction of NEC incidence	Reduction in episodes of feeding intolerance <i>or</i> reduction in time to full enteral feeding
Rojas et al. 2012	750	<b>37 %</b>	<b>43 %</b>
Oncel et al. 2014	400	<b>20 %</b>	<b>33 %</b>
Oncel et al. 2015	300	<b>22 %</b>	<b>36 %</b>
Shadkam et al. 2015	60	<b>82 %</b>	<b>24 %</b>
Hernandez-Enriquez et al. 2016	44	<b>83 %</b>	<b>17 %</b>
Indrio et al. 2017	60		<b>44 %</b>
Spreckels et al. 2018	104	<b>55 %</b>	
Wejryd et al. 2019	134	<b>17 %</b>	<b>0 %</b>
Hunter et al. 2012/Dimaguila et al. 2013	354	<b>89 %</b>	
Jerkovic-Raguz et al. 2016	100	<b>50 %</b>	
Sanchez-Alvarado 2017	225	<b>64 %</b>	
Kaban et al. 2019	94	<b>100 %</b>	<b>67 %</b>
Rolnitsky et al. 2019	1,357	<b>55 %</b>	<b>52 %</b>
Cui 2019	93	<b>75 %</b>	<b>18 %</b>

### Development Plan

The development plan for IBP-9414 consists of two clinical trials: the completed safety and tolerability study followed by the ongoing pivotal Phase III study, The Connection

Study. The safety and tolerability study, was been completed on time in Q4 2017. The Connection Study was initiated in the first half of 2019.

The first study was a randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 in premature infants (ClinicalTrials.gov identifier: NTC02472769). The study included 120 premature infants, defined as a gestational age  $\leq 32$  weeks and birth-weight ranging from 500 to 2,000 grams, recruited and randomized to receive either IBP-9414 or placebo. The first dose of study drug was administered within 48 hours of birth and continued daily for a period of 14 days. Follow-up assessments were occasionally made up to six months after the last dose of the study drug. The primary outcome in this trial was safety and tolerability. This Safety and Tolerability study has been completed on time in Q4 2017. The safety and tolerability study concluded that IBP-9414 was safe and well-tolerated in premature infants with birth weights between 500–2,000 grams, with high compliance to treatment with the study drug and that there was no evidence of cross-contamination with IBP-9414 in placebo treated infants.

The ongoing pivotal Phase III study is designed to demonstrate and document efficacy of IBP-9414 over placebo in the prevention of NEC and improvement of so called “feeding tolerance” in premature infants with a birth weight  $\leq 1,500$  grams. This study will also include safety evaluation.

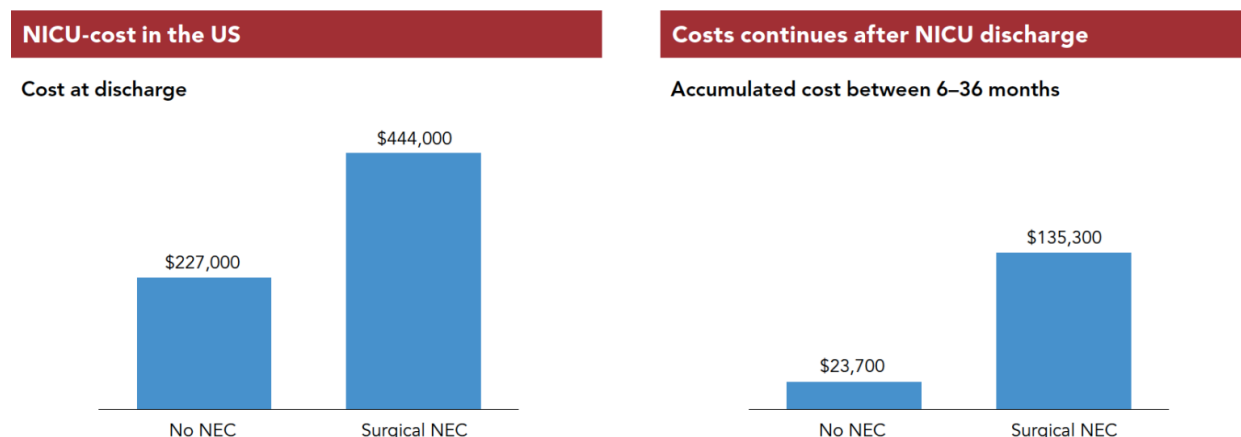
Given the urgency to provide an effective preventative therapy to this unmet medical need, IBT plans to utilize the available FDA and EMA expedited programs to reach the market as soon as possible.

### *Medical Need and market*

There has been little or no progress in recent years in improving outcomes for infants that are affected by NEC once the disease is underway. Nor is there definitive treatment that modifies the underlying risk factors for the disease. Approximately 20 to 40 percent of patients with NEC will require surgery. Thus, NEC prevention strategies are vital and urgently needed but to date none have been successful or generally adopted as the standard of care. Subsequently, a preventive treatment against NEC remains an unmet medical need.

NEC patients require medical care and in many cases also surgical interventions that increase hospital expenditures and prolong length of stay. The economic burden of NEC has been evaluated to be almost 20 percent of the total cost of the initial care of all newborns in the US, and represents approximately USD 5 billion spent annually on NEC. Moreover, those infants who survive NEC may face serious lifelong sequelae, which eventually decrease their quality of life and generate further costs to the patient and society. In the light of this, a preventive therapy for NEC such as IBP-9414 would therefore be expected to both directly and indirectly reduce these healthcare expenses.

IBT intends to demonstrate these benefits to support reimbursement for IBP-9414 in the prevention of NEC from caregivers, insurance companies and pharmaceutical authorities.



In September 2016 an independent consultant company, ClearView Healthcare Partners LLC (“ClearView”), were commissioned by IBT to evaluate the market need for the preventative drug IBP-9414 for NEC (the “ClearView Report”). ClearView completed 31 interviews with neonatologists and hospital Pharmacy and Therapeutics (“P&T”) committee members in the US.

The Clearview report established that neonatologists perceive NEC to represent a key priority despite its low incidence. The neonatologists nearly unanimously stated a need for improved prevention of NEC to relieve both the clinical and economic burdens.

Clearview also report that the majority of neonatologists do not recommend food supplements to prevent NEC due to safety-and efficacy reasons. The ClearView Report estimated that the number of premature infants eligible to receive prophylaxis for NEC is over 56,000 infants per annum in the US.

A target product profile (“TPP”) was presented to interviewees in the interviews conducted by Apex and Clearview. The TPP defined among other things the safety profile, method of administration, and expected efficacy in the prevention of NEC of 33%.

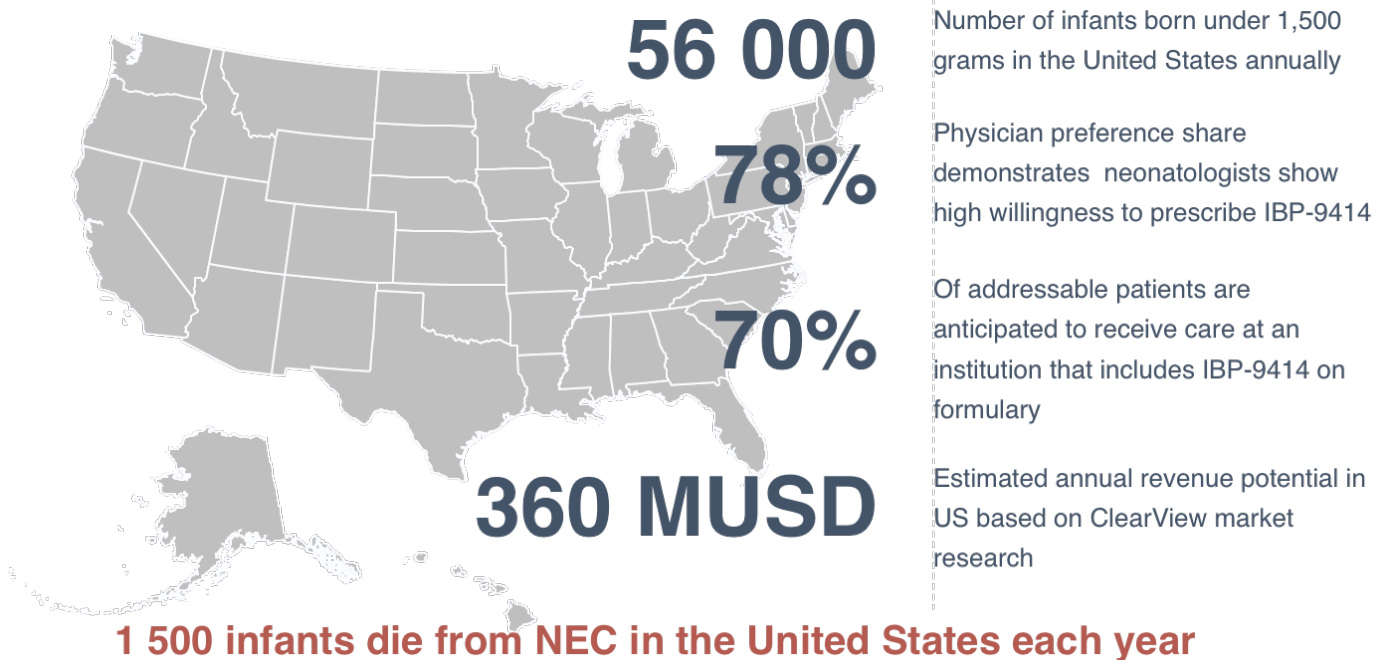
The ClearView Report has shown that when presented with the TPP of IBP-9414, neonatologists reacted positively and expressed a strong willingness to use IBP-9414 in their clinical practice (78 percent of Physician Preference Share), and a majority of P&T (Pharmacy and therapeutics) members expressed willingness to adopt the product.

In the Clearview Report, an adapted gestation age dependent price range was tested. Assuming a price of USD 3,000 per week of treatment until the infant reaches 34 weeks PMA, Clearview estimates 48 percent market penetration and sales to be USD 360

million per year in the USA. The analysis considered number of addressable patients, physician preference scores, formulary inclusion and protocol access.

## A valuable pharmaceutical

Results of market analysis by ClearView Healthcare Partners



Improvement of “feeding tolerance” is an important part of treating premature infants. In addition to the psychological benefit to the entire family of allowing the release of the infant from the hospital and returning home there is also significant economic benefit.

Expected improvements in feeding tolerance due to IBP-9414 and associated improved growth and development of the preterm infant are expected to lead to a reduced number of days of hospitalization. Evidence from earlier clinical experience in randomized, controlled clinical trials show that duration of hospitalization was significantly reduced with the same strain of *L. reuteri*.

Length of hospital stay is a strong marker for resource utilization. The costs of hospitalization are significantly higher, and the length of hospital stay are more than 6-fold greater for infants born <1000g birth weight, than for their late preterm counterparts and the costs for an extremely premature (<28 weeks gestational age) infant in a US NICU were estimated to be around USD 3,200 per day.

IBT intends to evaluate the market potential of the IBP-9414 within the additional indication area “feeding tolerance”.



## IBP-1016

Gastroschisis is a rare, life-threatening and debilitating birth abnormality in infants where the infant is born with externalized intestines.

After the initial surgical repair, gastroschisis represents an area of significant unmet medical need with no definitive treatment available. Post-operative management of gastroschisis is largely aimed at overcoming the significant morbidity related to the reduction in gut motility and consequent feeding intolerance necessitating the prolonged requirement for parenteral nutrition. Infants suffering from gastroschisis have a greatly increased risk of sepsis and liver cholestasis. It is common for neonates born with gastroschisis to have typically an extended hospital stay of 1-5 months thereby causing significant burden to the healthcare system.

The active bacteria used in IBP-1016 is known to enhance gut motility and function in infants with feeding intolerance.

## INTELLECTUAL PROPERTY

IBP-9414 is protected by already approved patents on *Lactobacillus reuteri*, held by BioGaia. IBT has been granted from BioGaia an exclusive royalty-free license to use *Lactobacillus reuteri* in IBT's areas of interest. The license is valid for the duration of the patent term.

IBT has and intends to apply for patent protection for innovations for the purpose of securing a sufficient and efficient protection of IBT's current and future commercial position and interests. Patent applications regularly cover the US, the EU, Japan and China, but also other markets where it is commercially justified.

The patent protection granted in the US is valid until 2026 and in Europe, China and Japan until 2027. Thereafter patent term extensions are possible in certain areas of the world which could provide additional patent protection of the innovation via patent term extensions.

IBT has filed for further patent protection for IBP-9414 which aims to protect patents until 2036. On February 9 we announced that the Japan Patent Office has issued a decision to grant a patent entitled: "A method of activating lactic acid bacteria", which protects the formulation of *Lactobacillus reuteri* including IBP-9414. The Japanese patent is valid until 2036.

## DIRECTORS REPORT

The Board of Directors and CEO of Infant Bacterial Therapeutics AB (publ) ("IBT"), reg. no. 556873-8586 hereby presents the Annual Report for the financial year January 1, 2020 to December 31, 2020.

This financial report is prepared in accordance with RFR 2, Reporting for legal entities and "Årsredovisningslagen".

## OPERATIONS

IBT is a clinical stage pharmaceutical company with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. IBT is currently developing its drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and improve so called "feeding tolerance" affecting premature infants. IBP-9414 contains the active ingredient *Lactobacillus reuteri*, which is a human strain of bacteria found in breast milk.

The portfolio contains a second program, IBP-1016, for the treatment of gastroschisis, a rare and severe disease in infants. By developing these drugs, IBT has the potential to fulfill medical needs where there are currently no treatment therapies available.

The FDA and the European Commission have granted IBT Orphan Drug Designation, and the FDA have granted "Rare Pediatric Disease" Designation for IBP-9414 for the prevention of NEC.

## SIGNIFICANT EVENTS DURING 2020

- The COVID-19 pandemic affects our development work, for example, activation of hospitals, which has not occurred at the desired rate. As of the date of this annual report, approximately half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study currently does not take place at the desired rate
- IBT's clinical study application was approved in Israel in January, in Poland in October and in Bulgaria in November

## SIGNIFICANT EVENTS AFTER THE FISCAL YEAR

- On February 9 we announced that the Japan Patent Office has issued a decision to grant a patent entitled: "A method of activating lactic acid bacteria", which protects the formulation of *Lactobacillus reuteri* including IBP-9414. The Japanese patent is valid until 2036.
- On February 10 we announced that the company has reached an important milestone after recruiting 300 premature infants to the ongoing clinical Phase III study of IBP-9414. This also means that a safety analysis of these infants will take place in order to also recruit infants with a very low birth weight, which in turn is expected to significantly increase the recruitment rate. Furthermore it means that IBT has an opportunity to validate the study's second primary endpoint, "feeding tolerance", and redefine this if necessary.
- In response to the COVID-19 pandemic and the coronavirus, IBT is closely monitoring developments and is actively taking measures to minimize or limit affects thereof on the company's operations. IBT adheres to directives issued by Folkhälsomyndigheten, the WHO and ECDC (European center for prevention and control of disease). The pandemic affects the recruitment level in IBT's pivotal study, "The Connection study". The bulk of the costs for conducting the study are generated in connection with recruitment of patients, and thus the assessment is that IBT has sufficient funds to conclude the study although at a later point in time.

## SELECTED FINANCIAL DATA

ooo's	2020 Jan-Dec	2019 Jan-Dec
Net sales	-	-
Operating profit/loss	-71 918	-47 200
Result after tax, SEK	-72 007	-46 320
Total assets	450 318	518 273
Cash flow for the period (SEK)	-56 625	-51 301
Cash flow per share for the period (SEK)	-5.04	-4.57
Cash	423 438	495 188
Earnings per share before and after dilution (SEK)	-6.41	-4.13
Equity per share (SEK)	39.21	45.46
Equity ratio (%)	98%	98%

## FINANCIAL DEVELOPMENT

Amounts are reported in KSEK (SEK in thousands). Amounts in parenthesis refer to the same period in the previous year unless stated otherwise.

### Result

Operational result amounted to -71 918 (-47 200) KSEK and result after financial items amounted to -72 007 (-46 320) KSEK.

Result after tax amounted to -72 007 (-46 320) KSEK.

Result per share before and after dilution amounted to -6.41 (-4.13) SEK.

### Costs

Costs for the IBP-9414 clinical trial are reported net of exchange rate effects on foreign currency deposits which exist for the purpose of securing future outflows. Exchange rate losses/gains during the reporting period amounted to -15 125 (4 319) KSEK (Notes 1, 2).

Operational costs amounted to 57 105 (51 519) KSEK prior to exchange rate losses/gains on currency deposits and after exchange rate losses/gains to 72 230 (47 200) KSEK.

Costs for the ongoing IBP-9414 clinical trial amounted to 32 910 (30 885) KSEK prior to exchange rate losses/gains.

Personnel costs amounted to 19 910 (16 770) KSEK. Bonuses paid during the reporting period amounted to 2 849 (889) KSEK.

Other external costs amounted to 4 285 (3 864) KSEK.

Operational costs increased during the reporting period compared to the previous year as the company's manufacturing costs for clinical trial material increased as well as increased costs for recruitment and dosing in the ongoing phase III study initiated in 2019.

Other external costs during the year increased compared to the same period in the previous year primarily resulting from increased consulting fees.

Personnel costs have increased during the reporting period in comparison to the equivalent period during the prior year due to bonuses amounting to 2 909 (889) KSEK. Net proceeds amounting to 1 747 KSEK were in their entirety paid to the company during the reporting period for issued warrants.

The company had 10 (9) full time equivalent employees. The company had 10 (11) employees on the balance sheet date.

### *Cash flow*

Cash flow for the period amounted to -56 605 (-51 301) KSEK. Cash flow per share amounted to -5.04 (-4.57) SEK.

### *Financial position*

Prepaid expenses amounted to approximately SEK 12.4m (9.4). The increase refers to contractual milestone payments paid to the company's CRO regarding unfulfilled obligations and are reported as receivable in the balance sheet.

Accrued expenses amounted to approximately SEK 6.9m (6.4). The increase refers to research and development costs.

The Company's cash balance on December 31, 2020, amounted to 423 438 KSEK compared to 495 188 KSEK on December 31, 2019.

The Company's shareholder's equity on December 31, 2020, amounted to 440 154 KSEK compared to 510 397 KSEK on December 31, 2019. Shareholder's equity per share on December 31, 2020 amounted to 32.91 compared to 45.46 SEK on December 31, 2019.

The Company's equity ratio on December 31, 2020 amounted to 98% compared to 98% on December 31, 2019.

IBT has during November 2017 and 2018 generated approximately SEK 528m after transaction costs in new share issues. Capital thus generated is deemed sufficient to conduct the ongoing Phase III clinical study, as well as to fund the company's activities until application for market approval.

## *Prospects for 2021*

The development plan for IBP-9414 is comprised of a clinical program consisting of two clinical trials: the completed safety and tolerability study and the ongoing pivotal Phase III study, “The Connection Study”. The Safety and Tolerability Study was completed on schedule during the fourth quarter of 2017. The following pivotal study, “The Connection Study”, commenced on July 4, 2019.

The primary goal in the first trial was to evaluate safety and tolerability. This study was completed on time in Q4 2017 and concluded that IBP-9414 was safe and well-tolerated in premature infants with birth weights between 500–2,000 grams, with high compliance to treatment with the study drug and that there was no evidence of cross-contamination with IBP-9414 in placebo treated infants.

The ongoing pivotal Phase III study is designed to demonstrate and document efficacy of IBP-9414 over placebo in the prevention of NEC and the improvement of so called “feeding tolerance” in premature infants with a birth weight  $\leq$  1,500 grams. This study will also include safety evaluation. Prior to initiation of “The Connection Study”, IBT and the FDA agreed to conduct a pilot analysis of the initial 300 patients with the objective to assess quality and quantity of clinical relevance of the premature infant’s ability to as early as possible assimilate enteral feeding without complications. In cooperation with independent experts in neonatal care connections are sought in “feeding tolerance” and infections such as sepsis (blood poisoning). In accordance with the FDA agreement the objective with the pilot analysis is to validate the study’s second primary endpoint and also to redefine it as needed.

As a consequence of the COVID-19 pandemic the study is delayed and is as previously communicated currently expected to be concluded in 2022.

## *RISKS AND UNCERTAINTIES*

### *Risk management and control*

The Company’s Board of Directors work continually and systematically with risk assessment to identify risks and take the necessary actions to cope with them. The internal control environment as described in the Company code of conduct report comprises mainly the following components: control environment, risk assessment, control activities, information and communication, as well as monitoring. For every identified significant risk, risk mitigation actions are formulated.

### *Dependent on development of one product*

The value of the Company is largely dependent on success in the Company’s development of IBP-9414 and the successful completion of clinical trials and the grant of a marketing authorization by the US Food and Drug Administration (“FDA”) and/or the European Medicines Agency (“EMA”). IBT’s clinical development is at development

stage and there is a risk that IBP-9414 will not demonstrate the required effect. If the development on IBP-9414 is unsuccessful, IBT may try to focus on other projects but there is a risk that such projects will not be successful.

### *Patents and trademarks*

BioGaia has been granted IBT an exclusive license to the BioGaia patent for use *Lactobacillus reuteri*, DSM17938, in developing of a medicinal remedy for treatment of premature infants. There are no royalties payable by IBT to BioGaia when commercializing IBT's pharmaceutical candidates.

The main patent protection for IBP-9414 is the product claim for the use of a specific strain of *Lactobacillus reuteri*. This is a claim-type which is often referred to as “unlimited product protection” similar to that used for new chemical entities in the relation to small-molecules based products in the pharmaceutical industry. Patents including a product claim for the strain are issued in most important markets. The patent protection granted in the USA, China and Japan are valid until 2026 and in Europe until 2027. After those years patent term extensions are possible in certain areas of the world which could provide additional patent protection of the innovation.

IBT has also applied for further patent protection relating to IBP-9414 which is currently pending and aim to further protect IBP-9414 until 2036. On February 9 we announced that the Japan Patent Office has issued a decision to grant a patent entitled: “A method of activating lactic acid bacteria”, which protects the formulation of *Lactobacillus reuteri* including IBP-9414. The Japanese patent is valid until 2036.

There is an inherent risk within the type of business that IBT conducts that the company's licenses, patents, trademarks or other non-tangible assets do not provide sufficient protection for the company, or the company's rights may not be upheld. Furthermore, patent infringement may occur which may involve costly litigation. Results from infringement cannot be guaranteed. Negative outcome from litigation regarding non-tangible assets may cause the losing party to lose protection, future use of said rights being prohibited, or the obligation to pay for damages. The company has filed patent applications for products under development, which have not yet been granted. There is no guarantee that such applications will be granted.

### *Regulatory risk*

IBT develops medicinal products and is dependent on assessments and decisions by applicable authorities. Such assessments are preceded by decisions, among other, regarding permission to conduct clinical studies, permission to market and sell pharmaceuticals, prerequisites for prescribing pharmaceuticals, pricing of pharmaceuticals subject to reimbursement systems, and discounts on pharmaceuticals.

It cannot be guaranteed that IBT will obtain the authoritative decisions necessary to conduct clinical studies and receive market approval.

It cannot be excluded that national authorities may take a contrary view or act to stop the product being sold in the applicable country, which could lead to delays or withdrawal of market approval.

To mitigate the regulatory risks IBT involves world-leading external expertise in relation to, for example, regulatory matters or the design of clinical studies.

### *Production*

IBT utilizes contract manufacturers for production of IBP-9414 which makes the Company dependent on external deliveries meeting agreed requirements for example for quality, quantity and time of delivery. There is no guarantee that IBT will not be impacted by delayed or failed deliveries, which could impact the progress of the clinical studies. To minimize this risk, IBT has evaluated a number of contract manufacturers that are able to produce IBP-9414.

### *Product liability and insurance*

IBT conducts development of pharmaceutical products and conducts clinical studies which causes risks related to product liability. To mitigate such risk, IBT carries insurance coverage for products under development. There is however no guarantee that the insurance coverage provides sufficient protection against claims for damages for eventual damages caused by the company's products or product candidates.

The Company's insurance policies include coverage for patients who participate in clinical trials and product liability insurance for products under development and in the market. The insurance coverage is subject to continuous review. The Company deems that the Company's insurance coverage is appropriate for the current scope of the business.

### *Dependence on key persons*

IBT is, to a high degree, dependent on a few key persons, both employees as well as directors. The Company's future earnings are affected by its ability to attract and retain qualified key persons. In cases where one or more key persons leave the Company and the Company is not successful in replacing such persons, this might have a negative effect on the Company's business, financial position and earnings.

### *Financial Risks*

IBT's operations are capital intensive.



IBT has during November 2017 generated SEK 104.5m in a directed share issue to institutional investors and SEK 439.1m in a preferred share issue in January 2018. Capital generated amounted to approximately SEK 544m before share issue costs and approximately SEK 528m after share issue costs, and is deemed sufficient to conduct the planned Phase III study.

A predominant share of IBT's development costs are commitments in foreign currencies. Should the SEK depreciate versus the specific currency, it could have a significant impact on the Company's financial position and results. The currency against which IBT has the greatest exposure is USD.

IBT's balance sheet item "cash and cash equivalents" in the balance sheet represents cash deposits at Danske Bank and SEB. The Company's assessment is that the counterpart risk at Danske Bank and SEB is very low. See note 18 for further information about financial risks.

IBT has declared taxable losses which may be nullified should the company be subject to new ownership controlling in excess of 50% of the votes of the company, or new owners who each control in excess of 5 % of the votes and collectively control in excess of 50% of the votes of the company. Nullification of these taxable losses would result in economic loss for IBT which may have a negative impact on the company's results and financial position.

In response to the COVID-19 pandemic and the coronavirus, IBT is closely monitoring developments and is actively taking measures to minimize or limit affects thereof on the company's operations. IBT adheres to directives issued by Folkhälsomyndigheten, the WHO and ECDC (European center for prevention and control of disease). The pandemic affects the recruitment level in IBT's pivotal study, "The Connection study". The bulk of the costs for conducting the study are generated in connection with recruitment of patients, and thus the assessment is that IBT has sufficient funds to conclude the study although at a later point in time.

Further information on risks and uncertainties is available in IBT's Rights Issue Prospectus dated January 10, 2018 on the Company's homepage [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

## *ENVIRONMENTAL RESPONSIBILITIES*

The Company's operations do not have any specific environmental risks and is not subject to notification obligations under the Swedish Environmental Code. The Board of Directors of the Company is of the opinion that the Company is in compliance with applicable rules and regulations and offers its employees a sound and safe working environment.

## *SUSTAINABILITY*

IBT should be perceived as an innovative and creative Company that represents quality, health and provides a function in society. It is important for IBT to work actively with sustainability issues. Respect for human rights, environment and anti-corruption shall reflect the company's operations with regard to business strategies, financing, investments and purchasing processes. The Company is not legally required to publish a sustainability report.

## *LEGAL PROCEEDINGS*

IBT is not and has never been involved in any legal proceedings.

## *CORPORATE GOVERNANCE*

The company's Corporate Governance Report for 2019 is published on the Company's webpage [www.ibtherapeutics.com](http://www.ibtherapeutics.com)

## *PUBLICATION*

IBT strives to have good communication with the Company's shareholders. The Company's publication of information should be correct, pertinent, and timely. The Company's communication will also be characterized by openness and the Company will publish periodic interim reports and annual reports in Swedish and English. Events which are determined to have potential impact on the share price will be distributed as press release.

## *CALENDAR*

Interim report January – March 2021	May 4, 2021
Interim report January – June 2021	August 14, 2021
Interim report January – September 2021	October 29, 2021

## *ANNUAL GENERAL MEETING*

The Annual General Meeting for IBT will be held on May 4, 2021. Due to COVID-19 the AGM will be conducted by voting in advance in accordance with temporary laws. AGM with personal attendance or by proxy will therefore not take place this year.

## BOARD OF DIRECTORS RECOMMENDATION OF APPROPRIATION OF PROFITS

SEK	2020
<b>Recommendation of appropriation of profits or loss</b>	
The Board of directors propose that the following surplus:	
Income carried forward	-159 830 956
Surplus reserve	668 931 488
Result for the period	-72 006 966
<b>Total</b>	<b>437 093 566</b>
<b>Be appropriated as follows:</b>	
Income carried forward	437 093 566
<b>Total</b>	<b>437 093 566</b>

The board of directors recommend that no dividend be paid for fiscal year 2020.

Regarding results and financial position in general please refer to the following income statements and balance sheets with accompanying notes.

## INCOME STATEMENT

SEK 000	Note	2020 Jan-Dec	2019 Jan-Dec
Other income		312	-
Research and development costs	2,3,4	-72 230	-47 200
<b>Operating loss</b>		<b>-71 918</b>	<b>-47 200</b>
<b>Result from financial items</b>			
Interest income and similar profit/loss items		214	1 605
Interest expense and similar profit/loss items		-303	-725
<b>Result after financial items</b>		<b>-72 007</b>	<b>-46 320</b>
<b>Result for the year*</b>		<b>-72 007</b>	<b>-46 320</b>

\* Result for the year equals total comprehensive income

### Result per share

SEK			
Result per share, before and after dilution*		-6.41	-4.13
Number of shares, weighted average**		11 226 184	11 226 184
Number of shares at end of period **		11 226 184	11 226 184

\* There are no dilution effects

\*\*On December 31, 2020, allocation of emitted shares amounted to 377 736 A-shares carrying 10 votes per share and 10 848 448 B-shares carrying 1 vote per share

## BALANCE SHEET

SEK 000	Note	2020-12-31	2019-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible non-current assets</i>			
Activated development costs	6	12 150	12 966
Shares in subsidiary	7	50	50
<b>Total non-current assets</b>		<b>12 200</b>	<b>13 016</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Accounts receivable		99	-
Other receivables	8	1 856	713
Prepaid expenses and accrued income	9	12 725	9 356
<b>Total current assets</b>		<b>14 680</b>	<b>10 069</b>
Cash and cash equivalents	10	423 438	495 188
<b>Total current assets</b>		<b>438 118</b>	<b>505 257</b>
<b>TOTAL ASSETS</b>		<b>450 318</b>	<b>518 273</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital		3 060	3 060
<i>Unrestricted equity</i>			
Share premium reserve		668 931	667 167
Accumulated losses		-159 830	-113 510
Net loss for the year		-72 007	-46 320
<b>Total equity</b>		<b>440 154</b>	<b>510 397</b>
<b>Liabilities</b>			
<i>Current liabilities</i>			
Accounts payable		1 232	943
Other current liabilities		2 065	512
Accrued expenses and prepaid income <sup>1</sup>		6 867	6 421
<b>Total current liabilities</b>		<b>10 164</b>	<b>7 876</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>450 318</b>	<b>518 273</b>

## STATEMENT OF CHANGES IN EQUITY

SEK 000	Restricted equity	Unrestricted equity		
	Share capital	Share premium reserve	Accumulated losses incl. loss for the period	Total equity
<b>Opening equity on Jan 1, 2019</b>	<b>3 060</b>	<b>667 167</b>	<b>-113 510</b>	<b>556 717</b>
Net loss for the year			-46 320	-46 320
<b>Total comprehensive income</b>			<b>-46 320</b>	<b>-46 320</b>
<b>Closing equity on Dec 31, 2019</b>	<b>3 060</b>	<b>667 167</b>	<b>-159 830</b>	<b>510 397</b>
<b>Opening equity on Jan 1, 2020</b>	<b>3 060</b>	<b>667 167</b>	<b>-159 830</b>	<b>510 397</b>
Net loss for the year			-72 007	-72 007
<b>Total comprehensive income</b>			<b>-72 007</b>	<b>-72 007</b>
<b>Shareholder transactions</b>				
Warrants		1 764		1 764
<b>Closing equity on Dec 31, 2020</b>	<b>3 060</b>	<b>668 931</b>	<b>-231 837</b>	<b>440 154</b>

## STATEMENT OF CASH FLOWS

<b>SEK 000</b>	<b>2020 Jan-Dec</b>	<b>2019 Jan-Dec</b>
<b>Operating activities</b>		
Operating profit/loss	-71 918	-47 200
Interest income received	214	1 605
Paid interest costs	-303	-725
Adjustment for non - cash flow affecting items:		
Depreciation production process	816	816
Value variance currency forward contracts	15 125	-4 319
<b>Cash flow from operating activities before changes in working capital</b>	<b>-56 066</b>	<b>-49 823</b>
<b>Cash flow from changes in working capital</b>		
Increase (-)/Decrease (+) in operating receivables	-4 611	-2 700
Increase (+)/Decrease (-) in operating liabilities	2 288	1 222
<b>Cash flow from operating activities</b>	<b>-58 389</b>	<b>-51 301</b>
<b>Financing activities</b>		
Warrants	1 764	-
<b>Cash flow from financing activities</b>	<b>1 764</b>	<b>0</b>
<b>Cash flow for the year</b>	<b>-56 625</b>	<b>-51 301</b>
Unrealized exchange rate difference in cash	-15 125	4 319
Cash and cash equivalents at the beginning of the year	495 188	542 170
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR</b>	<b>423 438</b>	<b>495 188</b>

## NOTES

### *Note 1 Accounting principles*

This financial report is prepared in accordance with the Annual Accounts Act, "Årsredovisningslagen" and as stipulated by RFR 2 Reporting for legal entities. Adoption of RFR 2 means that IBT applies all IFRS and statements as adopted by the EU to the extent possible subject to the Annual Accounts Act, "Tryggandelagen" and considerations of the relation of reporting and taxation. Preparation of financial reports in agreement with RFR 2 requires application of some significant estimates regarding various evaluations and assessments of principles of items for accounting purposes.

IBT has no transactions to report under total comprehensive income and a statement to that effect is provided under the income statement.

The subsidiary, IBT Baby AB, was established in May 2017. During the second quarter of 2017 and third quarter of 2020 IBT Baby AB received warrants at no cost from the parent company, which during the second quarter have been sold to personnel employed by IBT at market price. Other transactions have not occurred. As the company was established with a share capital amounting to 50 KSEK and only incurred marginal establishment costs, consolidated income statement and balance sheet, in all material aspects, equal those of the parent company and therefore no consolidation has been made, supported by the Annual Accounts act, "Årsredovisningslagen 7 kap. 3a §".

IFRS 16 Leases. In January 2016, the IASB published a new leasing standard that will replace IAS 17 Leases and the related interpretations, IFRIC 4, SIC-15 and SIC-27. The standard requires that assets and liabilities attributable to all leases, with a few exceptions, be recognized in the balance sheet. This accounting treatment is based on the view that the lessee has a right to use an asset during a specific period of time as well as an obligation to pay for this right. For the lessor, the financial reporting will remain essentially unchanged. The standard is applicable for financial years beginning on January 1, 2019 or later. Early application is permitted. IBT presents financial reports for the corporate entity and has thus chosen not to adopt the leasing standards according to IFRS 16. IBT presents in accordance with items 2-12 in RFR 2 and leasing costs are reported as in the past, linear over the term of the lease.

#### Functional currency and reporting currency

IBT's functional currency is SEK. The financial statements are presented in SEK rounded to the nearest thousand unless otherwise stated. Rounding to thousands may result in incorrect amounts when summarized.



### Recalculation from foreign currency

Transactions in foreign currencies are converted into the functional currency at the exchange rates on the transaction date. Monetary assets and liabilities in foreign currencies are converted into the functional currency at the exchange rates on the balance sheet date. Exchange rate differences resulting from the conversion are reported in the financial items section in the income statement. Non-monetary assets and liabilities are normally reported at historical cost and converted to exchange rate at date of transaction.

### Financial instruments, IFRS 9

Financial instruments are reported at cost. Financial assets are deleted from the balance sheet when the right to receive cash flows from the instrument has ceased or been transferred and the Company has transferred in principle all risks and benefits associated with possession. Financial liabilities are deleted from the balance sheet when the liability in the agreement has been fulfilled or otherwise revoked.

### Classification and valuation

Financial assets are classified based on the business model in which the asset is placed and the cash flow character of the asset. If the financial asset is held within the framework of a business model with the objective to collect contractual cash flows (hold to collect) and the contractual terms relating to the financial asset at predetermined periods generates cash flows solely comprised of capital and interest on the capital amount outstanding the asset will be reported at accumulated cost.

If on the other hand the business model goal is met by both collecting contractual cash flows and selling financial assets (hold to collect and sell), and the contractual terms of the financial asset at determined periods generates cash flows solely comprised of payments of capital and interest on the capital amount outstanding the asset will be reported at fair value under other comprehensive income.

All other business models (other) where the purpose is speculation, carry for sale or where the cash flow character eliminates other business models are consequently reported at fair value in the income statement.

Financial assets are comprised of cash and derivatives. Cash is comprised of immediately available cash held by Swedish banks. The company applies the business model hold to collect regarding cash. Derivatives are valued at fair value in the income statement.

Financial liabilities are valued at fair value in the income statement provided they have a determined price upon which IFRS 3 applies, carry for trade or if initially identified as liabilities at fair value in the income statement. Other financial liabilities are valued at accumulated cost.

### Write downs

The company reports loss reserves for expected credit losses on financial assets valued at accumulated cost. On each balance sheet date the company reports changes in expected credit losses since initial reporting in the result.

The company values the credit losses for all financial assets amounting to 12 months expected losses. For financial assets with significant increase in risk since the initial reporting a reserve is reported based on credit losses over the entire duration of the asset (the general model).

The company reports expected credit losses for the remaining duration of all financial instruments with significant increase in risk since the initial reporting, either estimated individually or collectively, considering all reasonable and verifiable information, including forward looking. The company evaluates expected credit losses from financial instruments in such manner that reflects objectively and by likelihood amounts ascertained by assessing an interval of possible outcomes, discounted value of money and reasonable and verifiable information regarding present conditions and forecasts regarding future economic conditions.

Cash is subject to the general model for write downs. The exemption for limited credit risk on the balance sheet date applies to cash.

The company defines default as if it is deemed unlikely that the counterparty will meet its obligations due to indications of financial difficulty and passed due payments. Default is regardless deemed to be the case when payment is 90 days past due. The company will delete a receivable when no further possible cash flows are deemed to exist.

### *Accounts payable*

Accounts payable are commitments to pay for goods or services acquired in operations from suppliers. Amounts are unhedged and normally payable within 30 days. Accounts payable are classified as current liabilities when due within one year or sooner (or a normal cycle of operation if longer). If not, they are reported as long-term debt. Liabilities are initially disclosed at Fair value and thereafter at accrued cost applying the effective interest method.

### *Other liabilities*

Expected duration for other liabilities is short, and therefore the liability is disclosed at nominal amount without using the discounting method for accrued cost.

### *Accounts receivable and other receivables*

Accounts receivable are reported at nominal value. Other receivables are reported at nominal value. Fair value of accounts receivable and other receivables equals reported value as the discounting effect is not material.

### *Non-current fixed assets*

IBT's development of internally generated non-current fixed assets are separated in a research phase and a development phase. All costs related to the research phase are reported as costs as they are incurred. All costs related to development are reported as assets according to IAS 38 if all the following criteria are met:

- the technical and commercial feasibility of the product or process has been established so it may be used or sold
- the Company intends and is able to complete the intangible asset and either use it or sell it
- there are prevailing conditions to use or sell the intangible asset
- It should be probable that the future economic benefits attributable to the asset will flow to the Company
- the Company has adequate recourses in accordance with its current finance plan to complete development
- the cost of the asset can be reliably measured

Costs related to the project are charged to income in the development phase should the above criteria not be met.

IBT's assessment is that development of the production process for the pharmaceutical candidate IBP-9414 meets the above criteria. Costs generated by the project have been activated as of the point in time the criteria were met. The production process has been assessed as completed for accounting purposes. The intangible asset "production process" is therefore depreciated over its estimated time of use and has caused depreciation costs in 2016. Estimated useful life is 20 years. Depreciation is reported in the R&D function in the income statement.

The currently ongoing development project, IBP-9414, is not deemed to meet the above criteria in IAS 38 to be activated as development in the balance sheet. The development costs are therefore charged to income as incurred.

### *Impairment of non-financial assets*

Non-financial assets with uncertain periods of use or non-financial assets not ready for use, are not depreciated but tested annually, or upon indication of impairment, for possible impairment. Assets which are depreciated are evaluated regarding impairment any time events or changes in circumstances indicate that the reported value may not be recovered. Write downs are made by such amounts that reported value exceeds recoverable value. Recoverable value is the higher of the assets Fair value reduced by sales costs and its useful value. Estimated impairment requirements are grouped for assets at lowest possible levels where most significant independent cash flow exists (cash generating groups). For assets (other than goodwill) previously impaired a test is made at each balance sheet date if recovery should be made.

### *Liquid assets*

Liquid assets in the balance sheet are comprised of cash and bank deposits.

### *Employee compensation*

Employee compensation in the form of salaries, bonuses, paid vacation, paid sick leave, and pension benefits are reported as earned. No pension commitments exist in the Company in addition to pension premiums paid annually. All pension plans are fee based.

### *Cash flow statement*

The cash flow is prepared according to the so called indirect method.

### *Income*

Income is reported at Fair value received or to be received. The company had no income as of the balance sheet date.

### *Leasing*

Leasing where a significant part of risk and benefits with ownership are retained by the seller are classified as operational leasing. Payments made during the term of lease are charged to income in the income statement on a linear basis over the term of lease.

### *Segment reporting*

Operational segments are reported in a method consistent with internal reporting provided to the highest executive decision maker. The Board of Directors are the Company's highest executive decision maker. The Company's operations are comprised

of only one branch of operation – to develop pharmaceutical products. The Company's report of total comprehensive income and financial position is solely one operating segment.

## *Taxes*

The Company's reported tax costs or tax income refers to current tax and changes in deferred taxes. Current tax is calculated based on taxable income for the period in accordance with prevailing tax laws. Current tax also includes adjustments from prior years.

IBT's taxable losses amount to approximately 260 (188) MSEK. Deferred taxes are reported for all temporary differences generated between the taxable value of assets and liabilities and their reported values. Deferred tax receivables are reported to the extent that it is likely that future taxable profits will be available, against which temporary differences may be offset. Deferred tax receivables in the company's financial statements will be activated only when it is certain that taxable income will occur. No deferred tax receivable is reported in the company's financial statements.

## *Significant assessments and estimates*

Assessments and estimates are appraised continuously and are based on historical experience and other factors, including expectations of future events considered to be reasonable under current circumstances. The Company makes assessments and estimates regarding the future. The resulting estimates for accounting purposes will, by definition, seldom equal the actual results. Assessments are also made regarding the Company's accounting principles.

The currently ongoing development project, IBP-9414, is not deemed to meet the above criteria in IAS 38 to be activated as development in the balance sheet. The development costs are therefore charged to income as incurred.

Amounts are reported in KSEK (SEK in thousands). Amounts in parenthesis refer to the same period in the previous year unless stated otherwise.

## *Note 2 Financial instruments*

Fair value of other receivables, cash, accounts payable and other liabilities are estimated to equal book value (accumulated cost) due to the short duration.

Financial assets and liabilities valued at fair value hierarchy 1 in the income statement. Profit and loss effects are reported in R&D function in the income statement .

All derivatives are valued at hierarchy level 2.

### Note 3 Leasing

IBT carries no financial leasing agreements. Leasing costs related to operational leasing are charged at cost over the leasing period.

Total future leasing costs regarding leasing agreements on the balance sheet date are as follows:

<b>Operational leasing</b>	<b>2020-12-31</b>	<b>2019-12-31</b>
<b>000's</b>		
Due for payment within one year	1 056	1 080
Due for payment within one and five years	2 462	929
<b>Total</b>	<b>3 518</b>	<b>2 009</b>

<b>Operational leasing costs during the year</b>	<b>2020</b>	<b>2019</b>
<b>000's</b>		
Rent	899	879
Parking	91	107
Automobiles	146	249
<b>Total</b>	<b>1 136</b>	<b>1 235</b>

### Note 4 Personnel

	<b>Average number of employees</b>			<b>Average number of employees</b>		
	<b>2020</b>		<b>Actual on Dec. 31</b>	<b>2019</b>		<b>Actual on Dec. 31</b>
	<b>Female</b>	<b>Male</b>	<b>Total</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Sweden	4	6	10	3	7	10
<b>Total</b>	<b>4</b>	<b>6</b>	<b>10</b>	<b>3</b>	<b>7</b>	<b>10</b>

<b>Gender</b>	<b>2020</b>			<b>2019</b>		
	<b>Female</b>	<b>Male</b>	<b>Total</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
	Board of Directors	3	3	6	3	2
Other management	0	5-	5	0	5	5
<b>Total</b>	<b>3</b>	<b>8</b>	<b>11</b>	<b>3</b>	<b>7</b>	<b>10</b>

<b>Total salaries, pension- and social costs, 000's</b>	<b>2020</b>	<b>2019</b>
Salaries and other compensation	14 370	10 761
Pensions	1 983	2 362
Social costs	3 222	3 187
Other costs	118	424
<b>Total</b>	<b>19 693</b>	<b>16 734</b>

Variable compensation to management amounted to SEK 1 955 (889)k

### *Board of Directors and committees*

Fees are paid in accordance with the decision taken at the annual general meeting.

### *Chief executive officer*

Base salary for the CEO, Mr. Staffan Strömberg, during 2020 amounted to SEK 2 355k plus SEK 336k in variable compensation. The company has a commitment regarding performance compensation upon completion of certain individual goals up to a maximum of SEK 0.8m.

The CEO has fee based pension compensation and the company has therefore no other pension commitments other than stated here. Pension premiums in 2020 amounted to 32.5 % of base salary.

The CEO and the company have a mutual notice period of six months. In addition, the company has a commitment of severance pay equal to nine months salary upon termination by the company.

## Other management

Compensation to other management is comprised of base salary, performance compensation, other compensation and pension premiums. Other management in the company refers to four persons who along with the CEO comprise the management group (Note 7).

The management group was in 2020 comprised of CEO Mr. Staffan Strömberg, COO Mr. Anders Kronström, CSO Mr. Eamonn Connolly, CMO Mr. Jonas Rastad and CFO, Mr. Daniel Mackey.

<b>Management compensation 2020</b>	<b>Base salaries/ fees</b>	<b>Performance compensation</b>	<b>Other benefits</b>	<b>Pension costs</b>	<b>Total</b>
<b>000's</b>					
Peter Rothschild, Chairman of the Board	645	-	-	-	645
Margareta Hagman, Board member	113	-	-	-	113
Eva Idén, Board member	113	-	-	-	113
Anthon Jahreskog, Board member	123	-	-	-	123
Robert Molander, Board member	113	-	-	-	113
Kristina Sjöblom Nygren, Board member	113	-	-	-	113
Staffan Strömberg, CEO	2 355	336	159	765	3 616
Other management (4)	4 783	1 619	112	856	7 369
<b>Total</b>	<b>8 358</b>	<b>1 955</b>	<b>272</b>	<b>1 621</b>	<b>12 206</b>



The management group was in 2019 comprised of CEO Mr. Staffan Strömberg, COO Mr. Anders Kronström, CSO Mr. Eamonn Connolly, CMO Mr. Jonas Rastad and CFO, Mr. Daniel Mackey.

<b>Management compensation 2019 000's</b>	<b>Base salaries/fees</b>	<b>Performance compensation</b>	<b>Other benefits</b>	<b>Pension costs</b>	<b>Total</b>
Peter Rothschild, Chairman of the Board	600	-	-	-	600
Margareta Hagman, Board member	100	-	-	-	100
Anders Ekblom, Board member	50	-	-	-	50
Anthon Jahreskog, Board member	100	-	-	-	100
Eva Idén, Board member	100	-	-	-	100
Lilian Wikström, Board member	100	-	-	-	100
Kristina Sjöblom Nygren, Board member	100	-	-	-	100
Staffan Strömberg, CEO	2 196	239	75	714	3 224
Other management (4)	4 679	650	112	1 035	6 476
<b>Total</b>	<b>8 025</b>	<b>889</b>	<b>187</b>	<b>1 749</b>	<b>10 850</b>

#### *Note 5      Audit fees*

<b>Deloitte AB, 000's</b>	<b>2020</b>	<b>2019</b>
Auditing	230	204
<b>Totalt</b>	<b>230</b>	<b>204</b>

Auditing refers to compensation for review of the company's internal controls, accounting, annual report and administration by the Board of Directors and CEO.

## Note 6 Intangible non-current assets

Activated development costs, 000's	2020	2019
Opening accumulated costs	16 225	16 225
Activated costs	-	-
<b>Total cost</b>	<b>16 225</b>	<b>16 225</b>
Opening accumulated depreciation	-3 259	-2 443
Depreciation	-816	-816
<b>Total accumulated depreciation</b>	<b>-4 075</b>	<b>-3 259</b>
<b>Carrying amount at end of the period</b>	<b>12 150</b>	<b>12 966</b>

Activated development costs refer to the production process of the pharmaceutical candidate IBP-9414. Period of use is based on the underlying useful life of the patent of 20 years.

Depreciation is linear from 2016 and is reported in the R&D-function in the income statement

### Impairment test

The criteria according to IAS 38 and IAS 36, respectively, require testing the immaterial fixed assets for impairment whenever events or changed circumstances indicate that the reported value may not be recovered.

Activated costs referring to the production process have been assessed. The company has at the time of disclosure of this financial report utilized the pharmaceutical candidate produced by the production process in a clinical Phase II study in which 120 patients were dosed.

Technology transfer possibility of the manufacturing method has been verified by third parties.

Two independent companies, Apex Healthcare Consulting Ltd., and Clearview Healthcare Partners have evaluated the market potential in 2014 and 2016, respectively, for IBP-9414 in the USA.

Their assessment of the market potential amounted to an interval of 200 MUSD to 360 MUSD per annum.

The total assessment is that the criteria in IAS 38 are met.

## Note 7 Shares in subsidiary

Name	Reg. No.	Domicile, country	No. Shares	Ownership	Book value 2020	Book value 2019
IBT Baby AB	559110-7353	Stockholm, Sweden	50 000	100%	50 000	50 000
<b>Total, SEK</b>					<b>50 000</b>	<b>50 000</b>

IBT Baby AB manages incentive programs for key personnel employed by IBT AB.

IBT issues warrants which are sold by IBT Baby AB to employees of IBT AB eligible to participate in the parent company's incentive program as follows:

### Share based incentive programs

#### WARRANTS 2017/2022

On May 4, 2017, the Annual General Meeting decided on an incentive program by designated issue of warrants to a subsidiary established for this purpose. The maximum number of warrants to be issued are 280 000.

The warrants were allotted in June 2017 at market terms at a price determined by calculating market price at the time of issue using the Black & Scholes method of valuation.

The holder of warrants may during the period from April 3, 2022 through May 3, 2022, for each warrant subscribe for one point one (1.1) new share in the company at a subscription price per share amounting to SEK 272.41 recalculated due to share issues in November 2017 and January 2018.

During 2017 a total of 200 000 warrants were issued and allotted. On January 1, 2020, 200 000 (200 000) warrants had been issued. The remaining 80 000 warrants were reserved for future employees.

The warrants are subject to first right of refusal stipulating that the warrants shall be sold back to IBT Baby AB should the employee, from the date of signing, terminate employment within one year by 100%, within two years by 75%, within three years by 50%, and within 4 years by 25%.

The warrants carry no dividend rights.

The warrants are issued at market value and have thus have not resulted in any benefits which require accruals for social costs in the parent company.

The subscription price per share exceeds the market price of IBT's share on the balance sheet date which means that the warrants do not cause any dilution when calculating result per share.

Total market value for the 200 000 issued warrants during the second quarter 2017 amounted to 884 KSEK.

During the second quarter 2020 a total of 50 000 warrants allotted. Total market price for the allotted 50 000 warrants during the second quarter 2020 amounted to 17 KSEK.

During the fourth quarter 2020 a total of 10 000 warrants allotted. Total market price for the allotted 10 000 warrants during the fourth quarter 2020 amounted to 27 KSEK.

On the balance sheet date December 31, 2020, a total of 260 000 (200 000) warrants had been allotted. The remaining 20 000 warrants are reserved for future employees.

Based on the existing number of shares the dilution resulting from the adopted incentive program, provided that all warrants are utilized for subscription of class B-shares, amounts to approximately 2.26 percent of shares, and 1.75 percent of votes.

<b>Ownership of warrants 2017/2022</b>	<b>Number allotted 2020-12-31</b>	<b>Number issued 2020-12-31</b>	<b>Number allotted 2019-12-31</b>	<b>Number issued 2019-12-31</b>
Staffan Strömberg, CEO	70 000	70 000	70 000	70 000
Eamonn Connolly	50 000	50 000	50 000	50 000
Daniel Mackey, CFO	50 000	50 000	50 000	50 000
Anders Kronström, COO	50 000	50 000	-	-
Other employees	40 000	40 000	30 000	30 000
<b>Total</b>	<b>260 000</b>	<b>260 000</b>	<b>200 000</b>	<b>200 000</b>

## **WARRANTS 2020/2024**

On June 16, 2020, the Annual General Meeting decided on an incentive program by designated issue of warrants to the subsidiary IBT Baby AB. The maximum number of warrants to be issued are 375 000. The warrants were allotted in September 2020 at market terms at a price determined by calculating market price at the time of issue using the Black & Scholes method of valuation.

The holder of warrants may during the period from July 1, 2024 through September 20, 2024, for each warrant subscribe for one point one (1) new class B share in the company at a subscription price per share amounting to SEK 400. On the balance sheet date December 31, 2020, a total of 185 025 warrants had been allotted. The remaining 189 975 warrants are reserved for future employees.

The warrants are subject to first right of refusal stipulating that the warrants shall be sold back to IBT Baby AB should the employee, from the date of signing, terminate employment within one year by 100%, within two years by 75%, within three years by 50%.

The warrants carry no dividend rights. The warrants are issued at market value and have thus have not resulted in any benefits which require accruals for social costs in the parent company. The subscription price per share exceeds the market price of IBT's share on the balance sheet date which means that the warrants do not cause any dilution when calculating result per share.

Based on the existing number of shares the dilution resulting from the adopted incentive program, provided that all warrants are utilized for subscription of class B-shares, amounts to approximately 1.62 percent of shares, and 1.25 percent of votes.

Total market value for the 185 025 issued warrants during the fourth quarter 2020 amounted to 1 721 KSEK.

<b>Ownership of warrants 2020/2024</b>	<b>Number allotted 2020-12-31</b>	<b>Number issued 2020-12-31</b>	<b>Number allotted 2019-12-31</b>	<b>Number issued 2019-12-31</b>
Staffan Strömberg, CEO	50 000	50 000	0	0
Eamonn Connolly	40 000	40 000	0	0
Daniel Mackey, CFO	20 588	20 588	0	0
Anders Kronström, COO	40 000	40 000	0	0
Other employees	34 437	34 437	0	0
<b>Total</b>	<b>185 025</b>	<b>185 025</b>	<b>0</b>	<b>0</b>

### Total number of allotted warrants

<b>Allotted warrants, year</b>	<b>Issued warrants</b>	<b>Strike price*</b>	<b>Value per allotted warrant</b>	<b>Volatility, %**</b>	<b>Risk-free interest, %</b>	<b>Value per share</b>	<b>Expiry, year</b>
2017 (2017/2022)	200 000	272*	4,42	40	-0,2	85	2022
2020 (2017/2022)	50 000	272*	0,35	40	-0,3	75	2022
2020 (2017/2022)	10 000	272*	2,66	40	-0,3	127	2022
2020 (2020/2024)	87 541	400	14,24	40	-0,3	170	2024
2020 (2020/2024)	97 484	400	4,86	40	-0,3	125	2024
<b>Total</b>	<b>445 025</b>	-	-	-	-	-	-

\*Recomputed from SEK 300 after directed share issue in November 2017

\*\*Expected future volatility is ascertained by comparison of historical average and median values for comparable listed companies in the same sector as IBT based on analysis in S&P Capital IQ.

### Note 8 Other receivables

<b>000's</b>	<b>2020</b>	<b>2019</b>
Taxes	1 464	713
Other receivables	392	-
<b>Total cost</b>	<b>1 856</b>	<b>713</b>

### Note 9 Prepaid expenses and accrued income

<b>000's</b>	<b>2020</b>	<b>2019</b>
Prepaid rent	54	54
Prepaid insurance clinical trial	250	1 435
Prepaid CRO costs*	12 211	7 793
Other prepaid expenses	210	74
<b>Total cost</b>	<b>12 725</b>	<b>9 356</b>

\*Contractual milestone payments paid to the company's CRO regarding unfulfilled commitments. The maximum credit risk exposure on the balance sheet date equals reported value.

## Note 10 Cash and bank deposits

000's	2020	2019
Bank deposits at Danske Bank and SEB	423 438	495 188
<b>Total cost</b>	<b>423 438</b>	<b>495 188</b>

The Company's liquidity consists solely of cash deposits held at Danske Bank and SEB. Total liquidity on the balance sheet date December 31, 2020, amounted to SEK 423.4m (495.2m) of which USD amounted to SEK 82.0m (122.0m) and EUR amounted to SEK 54.2m (62.6m).

Liquidity in SEK is charged with Deposit Fees. Deposits of USD and SEK on fixed term time deposits generate interest income reported under other financial income and expenses.

## Note 11 Accrued expenses and prepaid income

000's	2020	2019
R&D costs	2 966	3 720
Social costs and special salary taxes	1 867	937
Vacation pay	1 660	1 297
Salaries	70	169
Board fees	78	58
Other accrued expenses	240	240
<b>Total</b>	<b>6 867</b>	<b>6 421</b>

All accrued expenses are due for payment within twelve months.

## Note 12 Significant events after the reporting period

On February 9 the company announced that the Japan Patent Office has issued a decision to grant a patent entitled: A method of activating lactic acid bacteria, which protects the formulation of *Lactobacillus reuteri* including IBP-9414. IBT is currently developing its drug candidate IBP-9414 in Phase III for the prevention of NEC and improvement of feeding tolerance in preterm infants.

On February 10 the company announced that the company has reached an important milestone after recruiting 300 premature infants to the ongoing clinical Phase III study of IBP-9414. This in part means that a safety analysis of these infants will take place in order to also recruit infants with a very low birth weight, which in turn is expected to significantly increase the recruitment rate. Furthermore it means that IBT has an opportunity to validate the study's second primary endpoint, feeding tolerance, and redefine this if necessary.

In response to the COVID-19 pandemic and the coronavirus, IBT is closely monitoring developments and is actively taking measures to minimize or limit affects thereof on the company's operations. IBT adheres to directives issued by Folkhälsomyndigheten, the WHO and ECDC (European center for prevention and control of disease). The pandemic affects the recruitment level in IBT's pivotal study, "The Connection study". The bulk of the costs for conducting the study are generated in connection with recruitment of patients, and thus the assessment is that IBT has sufficient funds to conclude the study although at a later point in time.

No other significant events have occurred after the reporting period.

### *Note 13 Board of Directors recommendation of appropriation of profits*

<b>SEK</b>	<b>2020</b>
<b>Recommendation of appropriation of profits or loss</b>	
The Board of directors propose that the following surplus:	
Income carried forward	-159 830 956
Surplus reserve	668 931 488
Result for the period	-72 006 966
<b>Total</b>	<b>437 093 566</b>
<b>be appropriated as follows:</b>	
Income carried forward	437 093 566
<b>Total</b>	<b>437 093 566</b>

The board of directors recommend that no dividend be paid for fiscal year 2020.

### *Note 14 Related party transactions*

Mr. Anders Kronström has acquired warrants in warrant program 2017/2022 in the amount of 17 KSEK and in warrant program 2020/2024 in the amount of 347 KSEK. Warrants in warrant program 2020/2024 have been acquired by Staffan Strömberg in the amount of 338 KSEK, by Eamonn Connolly in the amount of 347 KSEK, and by Daniel Mackey in the amount of 253 KSEK.

Compensation to the Board of directors are paid in accordance with the annual general meeting.

The Chairman of the Board, Mr. Peter Rothschild, receives Board fees amounting to 200 KSEK per annum, and 400 KSEK annually as operational Chairman.

No other significant related party transactions have occurred.

### Note 15 Pledged assets and contingent liabilities

	2020	2019
Pledged assets and contingent liabilities	None	None

### Note 16 Result per share

Calculations are in accordance with IAS 33 Earnings per share. Earnings per share are calculated by dividing result for the period with the weighted average number of outstanding shares during the period.

Result per share, SEK	2020	2019
Result for the period, 000's	-72 007	-46 320
Weighted average number of shares before and after dilution*	11 226 184	10 788 914
<b>Result per share before and after dilution</b>	<b>-6.41</b>	<b>-4.13</b>

### Note 17 Share capital development (SEK)

Period	Transaction	Change	Series A shares	Series B shares	Share capital	Quota value	Subscription price	Total Invested
2011-11-22	Founding	50 000			50 000	1,00	1,00	50 000
2015-09-15	Share issue	40 000			90 000	1,00	1 320,00	52 800 000
2015-09-15	Bonus issue	90 000			500 000	5,56	-	52 850 000
2016-02-12	Split/reclass	-90 000	74 066	1 760 480	500 000	0,27	-	52 850 000
2016-05-30	Share issue	-	148 132	3 520 960	1 500 000	0,27	27,30	153 016 212
2017-11-30	Share issue	-	-	1 100 000	300 000	0,27	95,00	257 516 212
2018-02-05	Share issue	-	155 538	4 435 663	3 051 120	0,27	95	693 680 307
2018-02-13	Share issue	-	-	31 345	3 059 663	0,27	95	696 658 082
<b>Totalt</b>		<b>0</b>	<b>377 736</b>	<b>10 848 448</b>	<b>3 059 663</b>	<b>0,27</b>	<b>-</b>	<b>696 658 082</b>

### Note 18 Financial risk management

#### General

The financial risks related to the Company's operations are mainly liquidity, currency, and counterparty risks.



## *Liquidity risks*

Liquidity risks are such risks as not having access to liquidity to meet the Company's operational requirements. The Company has no financial liabilities with agreed duration. Other liabilities are commitments to pay for goods or services obtained during operations from suppliers. The amounts are unhedged and normally payable within 30 days. Capital needs are monitored by budget review.

## *Financing strategy*

The Company's capital requirements have previously been met by capital injections from its former parent company, BioGaia and share issue in connection with listing the Company on Nasdaq First North in March 2016. To date, IBT has received 82 MSEK from BioGaia and 100 MSEK from other shareholders in connection with the May 2016 share issue.

IBT has during November 2017 generated SEK 104.5m in a directed share issue to institutional investors and in January 2018, a preferred share issue generated SEK 439.1m. Capital generated amounting to approximately SEK 543.6m prior to transaction costs and approximately SEK 528m post transaction costs is deemed sufficient to conduct the planned pivotal Phase III clinical study.

As the Company's pharmaceutical candidate IBP-9414 reaches important milestones in its pharmaceutical development, additional financing possibilities are available. As a listed company in Sweden the Company can issue new shares with preemptive rights for its shareholders. Other possible financing methods are licensing specific rights to the pharmaceutical to pharmaceutical company partners and a share issue to new investors, conditional upon being possible on terms acceptable to current shareholders.

Obtaining loans for financing is not deemed suitable other than as a temporary solution before the Company reaches profitability and has positive cash flow. The company has only financial liabilities with short duration which are due for payment within 12 months.

Access to capital may be limited at times when needed by the Company.

## *Counter party risks*

The Company allows only investments in interest bearing instruments which carry low risk and high liquidity. The Company cooperates with established and credit worthy counterparties and evaluates receivables on an ongoing basis in order to achieve low exposure to bad debts. To mitigate this risk, IBT deposits its surplus liquidity in liquid accounts at Danske Bank and SEB. The Company had no short-term deposits on the balance sheet date.

## Currency risk

Currency risk is the risk of fluctuating values in assets or liabilities resulting from variations in exchange rates. The majority of IBT's development costs are commitments in foreign currencies. Should the SEK be reduced in value versus foreign currencies, it may have considerable impact on the Company's financial position and results. As of the balance sheet date, the Company has no currency hedges. The currencies against which IBT has the greatest exposure are USD and EUR.

A variance in the SEK versus USD and EUR of 5 percent, based on total research-and development costs, all else being equal, would have affected 2020 results by approximately SEK 1.6m.

## DEDUCTION OF CERTAIN KEY FIGURES

	2020 Jan-Dec	2019 Jan-Dec
<b>Cash flow per share</b>		
Cash flow for the year,, 000's	-56 625	-51 301
Average number of shares	11 226 184	11 226 184
<b>Cash flow per share (SEK)</b>	<b>-5.04</b>	<b>-4.57</b>
<b>Equity per share</b>		
Equity, 000's	440 154	510 397
Number of shares at end of year	11 226 184	11 226 184
<b>Equity per share (SEK)</b>	<b>39.21</b>	<b>45.46</b>
<b>Equity ratio</b>		
Equity, 000's	440 154	510 397
Total equity and liabilities, 000's	450 318	518 273
<b>Equity ratio %</b>	<b>98%</b>	<b>98%</b>

## FINANCIAL DEFINITIONS

<b>Key ratios</b>	<b>Definition</b>	<b>Motive</b>
<b>Average number of shares</b>	Average number of shares during the year	Relevant in calculating income and cash flow per share
<b>Net sales</b>	Sales for the year	Sales of services
<b>Reporting period</b>	January 1 - December 31, 2020	Defines time period comprised by this financial report
<b>Result per share</b>	Result for the year divided by average number of shares	Result allocated per share
<b>Cash flow per share*</b>	Cash flow for the year divided by average number of shares	Measure to describe cash flow allocated to one share during the year
<b>Number of shares*</b>	Number of shares at the end of the year	Relevant for calculating shareholders' equity allocated to one share
<b>Total assets</b>	Total assets at the end of the year	Relevant for calculating shareholder's equity
<b>Shareholders equity/share*</b>	Total shareholders' equity divided by the number of shares at the end of the year	Measure to describe shareholder's equity per share
<b>Equity ratio*</b>	Total shareholders' equity as a percentage of total assets	Measure to evaluate the company's ability to meet its financial obligations

\*The Company presents certain financial measures in the Year-end report not defined by IFRS. The Company deems that these measures provide valuable additional information for investors and management of the Company as they enable evaluation and benchmarking of the Company's performance. As all companies do not calculate financial measures the same way, these measures are not always comparable to those used by other companies. These financial measures shall therefore not be viewed as replacements for those defined by IFRS. The financial definitions are not defined by IFRS unless otherwise stated.

## *BOARD'S ASSURANCE*

The Board of Directors and CEO hereby certify that this report gives a true and fair presentation of the Company's operations, financial position and result of operations, and describes material risks and uncertainties facing the Company.

The Annual Report was approved for issuance by the Board of Directors on April 8, 2020 and will be subject to approval at the annual general meeting on May 4, 2021.

Stockholm, April 8, 2020

Peter Rothschild  
Chairman

Eva Idén  
Director

Margareta Hagman  
Director

Kristina Sjöblom Nygren  
Director

Anthon Jahreskog  
Director

Robert Molander  
Director

Staffan Strömberg  
CEO

Nb: This is a translation of the Swedish annual report. If any discrepancies exist, the Swedish version shall prevail.

Our Auditor's Report was submitted on April 8, 2021

Deloitte AB  
Birgitta Lööf  
Authorized public accountant

## *AUDITOR'S REPORT*

### **To the general meeting of the shareholders of Infant Bacterial Therapeutics AB (publ)**

**Corporate identity number: 556873-8586**

#### *Report on the annual accounts*

#### *Opinions*

We have audited the annual accounts of Infant Bacterial Therapeutics AB (publ) for the financial year 2020-01-01 - 2020-12-31. The annual accounts are included on pages 18-52 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position as of 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the company as of 31 December 2020 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the company.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's Board of Directors in accordance with the Audit Regulation (537/2014) Article 11.

#### *Basis for Opinions*

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the company in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its

controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### *Key Audit Matters*

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts as a whole, but we do not provide a separate opinion on these matters.

### *Research and development costs*

The company's costs for research and development as of December 31, 2020 amount to TSEK 72 230 after exchange rate gains on foreign currency forward contracts and currency deposits and is a significant amount in the income statement. It is management's assessment that the entire amount should be expensed instead of being capitalized as intangible assets since the criteria in IAS 38 regarding capitalization are not deemed to be fulfilled. The company describes its positions in the accounting principles on page 32.

Our audit procedures included, but were not limited to:

- Examination of a number of transactions to ensure correct classification
- Examination of the company's analysis and assumptions that form the basis of the company's written position for the question
- Examination that the required disclosures are provided in the annual accounts

### *Other information than the annual accounts and consolidated accounts*

The other information contains of the remuneration report and other information than the annual accounts and is found on the pages that does not include the annual report or the corporate governance statement. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise

obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

### *Auditor's responsibility*

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

A further description of our responsibilities for the audit of the annual accounts and consolidated accounts is located at the Swedish Inspectorate of Auditors website:

[www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar) This description forms part of the auditor's report".

## *Report on other legal and regulatory requirements*

### *Opinions*

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Infant Bacterial Therapeutics AB (publ) for the financial year 2020-01-01 - 2020-12-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit to be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### *Basis for Opinions*

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of the company in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.



## *Auditor's responsibility*

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act. A further description of our responsibilities for the audit of the management's administration is located at the Swedish Inspectorate of Auditors website: [www.revisorsinspektionen.se/rn/showdocument/documents/rev\\_dok/revisors\\_ansvar.pdf](http://www.revisorsinspektionen.se/rn/showdocument/documents/rev_dok/revisors_ansvar.pdf). This description forms part of the auditor's report.

## *The auditor's examination of the corporate governance statement*

The Board of Directors is responsible for that the corporate governance statement on pages 59-68 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared.

Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law

are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Acts.

Deloitte AB, was appointed auditor of Infant Bacterial Therapeutics AB by the general meeting of the shareholders on the 2020-06-16 and has been the company's auditor since 2014-03-29.

Stockholm April 8, 2021

Deloitte AB

*Signature on Swedish original*

Birgitta Lööf

Authorized public accountant

## *CORPORATE GOVERNANCE REPORT IBT AB 2020*

### *Compliance with the Swedish Code of Corporate Governance (Svensk Kod för Bolagsstyrning)*

The purpose of the Code is to strengthen confidence in Swedish listed companies by promoting a positive development of the company's corporate governance. The code is based on the principle of "comply or explain" which means that a company can make deviations from the code but these must then be explained.

IBT has not deviated from any of the rules specified in the Code.

#### ***Environment and responsibility***

IBT's operations do not pose any specific environmental risks and do not require any specific environmental permits or decisions from authorities. The Board of Directors believes that the company conducts its operations in accordance with applicable health and safety rules and offers its employees a safe and healthy working environment.

#### ***Diversity and gender equality***

IBT should be a workplace where diversity and gender equality are natural parts of the business. A workplace characterized by diversity and gender equality is necessary for IBT to be an attractive workplace and to achieve set goals. Recruitment shall be based on competence requirements, diversity and gender equality.

#### ***Sustainability***

IBT is to be perceived as an innovative and creative company, which stands for quality and health and plays a role in society. It is important for IBT to work with sustainability. Respect for human rights, the environment and anti-corruption must characterize our everyday lives through business strategies, financing processes, investments and purchases.

According to the Swedish Annual Accounts Act (Årsredovisningslagen), there is no requirement that the Company prepare a Sustainability Report.

### *Corporate governance at IBT*

IBT is a Swedish limited company whose B shares are listed on Nasdaq Stockholm. The company is governed by the AGM, the Board of Directors, the President and the executive management in accordance with the Companies Act, the Articles of Association, rules of procedure for the Board and the CEO's instructions and the Swedish Code of Corporate Governance. The Board is responsible for evaluating established goals and continuously evaluating IBT's financial position and earnings and evaluating the operational management.

The share capital consists of 377,736 Class A shares with 10 voting rights per share and 10,848,448 Class B shares with one voting right per share.

### *Articles of Association*

In accordance with IBT's articles of association, the Company will develop, manufacture, market and sell pharmaceuticals directly or through subsidiaries or other forms of part-ownership or partnerships and conduct related operations. The seat of the Board is Stockholm. The Articles of Association can be found on IBT's website under the heading Investors / Corporate Governance.

### *Annual General Meeting*

In accordance with the Swedish Companies Act, the Annual General Meeting is IBT's highest decision-making body and at the Annual General Meeting the shareholders exercise their voting rights on key issues, for example establishing a report on comprehensive income and financial position, disposition of IBT's results, granting discharge from the Board of Directors and the Board of Directors, election of the Board of Directors and the CEO. and remuneration to the Board of Directors and auditors. In addition to the AGM, an Extraordinary General Meeting can be called. In accordance with the Articles of Association, notice of the Annual General Meeting and Extraordinary General Meeting are published in Post- och Inrikes Tidningar and on IBT's website.

Annwall & Rothschild Investment AB, owns 7.02 percent of the capital and 28.63 percent of the votes in the company.

### ***Annual General Meeting 2020***

At IBT's Annual General Meeting on June 16, 2020, shareholders represented 61 percent of the total number of votes in the company. At the Annual General Meeting, the company's President, six Board members elected at the Annual General Meeting and the company's elected auditor were present.

The Annual General Meeting resolved, inter alia, the following:

- adoption of the annual report
- granted discharge for Board members and the CEO
- that no dividend is paid
- that the board shall consist of six members without deputies
- re-election of board members Margareta Hagman, Eva Idén, Anthon Jahreskog, Kristina Sjöblom Nygren, Peter Rothschild and election of Robert Molander
- re-election of Peter Rothschild as Chairman
- re-election of the registered accounting firm Deloitte AB

- that remuneration to be paid to the Chairman of the Board of SEK 250,000 and an additional remuneration for the work of Chairman of the Board of SEK 400,000 and to other members of the company not employed by SEK 125,000 each. Members of the compensation committee shall be paid remuneration amounting to SEK 40,000 for the Chairman and SEK 20,000 for each of the other members of the committee.
- that audit fees should be paid according to approved invoice
- on the nomination committee in accordance with the nomination committee's proposal, and
- on guidelines for remuneration to senior executives in accordance with the Board's proposal.

### ***The Annual General Meeting 2021***

The 2021 Annual General Meeting will be held on May 4.

### ***Notice of Annual General Meeting***

Notice of Annual General Meeting shall be made through advertising in Post- och Inrikes Tidningar and on the company's website. That notice should be announced in Svenska Dagbladet and on the company's website.

### ***Nomination Committee***

The Annual General Meeting 2020 resolved that a Nomination Committee should be appointed as follows: "The Chairman of the Board shall convene the three largest shareholders in the company, who each nominate a representative to be a member of the Nomination Committee together with the Chairman of the Board. At the composition of the nomination committee, the ownership conditions as of June 30, 2020 will determine which are the largest shareholders in terms of the number of votes. The representative of the largest shareholder in the nomination committee at this time shall be the chairman of the nomination committee. If one of the three largest shareholders waives their right to appoint a member to the nomination committee, the next shareholder in size shall be given the opportunity to appoint a member to the nomination committee."

The Nomination Committee has been formed in accordance with the decision of the Annual General Meeting and consists of, in addition to the Chairman of Infant Bacterial Therapeutics AB's Board of Directors, Peter Rothschild, Per-Erik Andersson, representative of the company's largest shareholder Annwall & Rothschild Investments AB, Sebastian Jahreskog, who via direct and indirect ownership is the company's second largest shareholder, and Jannis Kitsakis, representative of the company's third largest shareholder, Fourth AP-Fonden. All members of the nomination committee, except Peter Rothschild, are independent in relation to the company and company management.

The Nomination Committee shall prepare proposals on the following issues to be submitted to the Annual General Meeting 2020 for resolution:

- a) proposals for election of the Chairman of the Meeting
- b) proposals for the number of Board members
- c) proposals for election of the Chairman of the Board
- d) proposals for election of other Board members
- e) proposals for election of the auditor
- f) proposal for Board fees
- g) proposal for audit fees
- h) proposals regarding nomination committee for the 2021 Annual General Meeting.

All shareholders have had the opportunity to contact the Nomination Committee with proposals for members to the Board for further evaluation within the framework of its work. No comments or suggestions have been received by the Nomination Committee to date.

The Nomination Committee submits a written motivation to the Board to the Annual General Meeting. In its justification, the Nomination Committee takes into account the diversity and breadth of the Board and strives for an even gender distribution.

### *The Board*

According to IBT's Articles of Association, the Board shall consist of a minimum of three and a maximum of ten members and no deputies. The Board is elected annually at the AGM for the period until the end of the next AGM. The Board of Directors has since the Annual General Meeting 2019 consisted of six members elected by the AGM without deputies. Peter Rothschild is indirect shareholder in IBT through Annwall & Rothschild Investment AB. Other members are independent in relation to the company and company management.

The CEO is not a member of the Board but is adjunct to all Board meetings. Other officers in the company participate in Board meetings as rapporteur. The Board of Directors has adopted a rules of procedure, including the division of work between the Board and the CEO and the structure of the Board's work during the year. In addition to the responsibilities of the Swedish Companies Act and the Articles of Association is regulated following the Board's rules:

- Hold at least 4 board meetings, in addition to the statutory meeting
- Determine the overall objectives of the company's operations and decide on the company's strategy and evaluate the operational management and risk assessment in the company.
- Approve budget and corresponding long-term plans including investment budget

- Process matters relating to investments and the like in the amount of five hundred thousand (500,000 SEK) or other commitments for the company, which entails a cost to the company exceeding five hundred thousand (500,000 SEK)
- Decide on the purchase and sale of real estate, shares or acquisitions of another company's operations in excess of five hundred thousand (500,000 SEK)
- Determine the annual report, the directors' report and the interim reports
- Borrowing
- Enter into an agreement with a term of more than three years
- Initial processes of large scope and settlement of disputes of significant importance
- Other issues of significant economic or other importance

The Board of Directors is responsible for monitoring the Company's financial position, for monitoring the efficiency of the Company's internal control, internal audit and risk management, for keeping informed of the audit of the 2020 financial statements and for reviewing and monitoring the auditor's impartiality and independence.

In addition, the Board of Directors has adopted the CEO's instruction, certificate instruction including instructions regarding liquidity management and currency management policy. The work order, CEO instruction and attestation instruction are tested at least once a year.

## ***The Board of Directors presence in 2020***

Name	Position	Member since	Independent in relation to		Attendance 2020
			Company and senior management	Major shareholders	
Peter Rothschild	Chairman of the Board <sup>3</sup>	2011	No <sup>1</sup>	No <sup>2</sup>	8/8
Margareta Hagman	Board member	2015	Yes	Yes	8/8
Eva Idén	Board member	2017	Yes	Yes	8/8
Anthon Jahreskog	Board member <sup>3</sup>	2017	Yes	Yes	7/8
Robert Molander	Board member	2020	Yes	Yes	4/4
Kristina Sjöblom Nygren	Board member	2018	Yes	Yes	7/8

<sup>1</sup> In his role as working chairman, Peter Rothschild is not considered independent in relation to company.

<sup>2</sup> Peter Rothschild is a partner in Annwall & Rothschild Investments AB, the Company's largest shareholder.

<sup>3</sup> Member in Remuneration Committee. The Remuneration Committee has, besides ongoing contact, had two meetings during 2020 with full attendance.

If a member has not been able to attend a board meeting, this member has had the opportunity to present his / her views to the chairman before the meeting.

Board meeting agenda is as follows where appropriate:

- Business Plans
- Business follow-up
- Investments
- Strategy
- Performance reports
- Significant agreement
- Budget
- Financial statements

The Board continuously evaluates its work through open discussions and annually performs a written evaluation of its work. The Nomination Committee is informed of the results of the evaluation.



## *Remuneration of the Board*

The 2020 Annual General Meeting resolved on Board fees of SEK 250,000 to the Chairman and SEK 125,000 to other members. In addition, a decision was made on an additional fee of SEK 400,000 to the chairman in his assignment to be working chairman of the board. Members of the compensation committee shall be paid remuneration amounting to SEK 40,000 for the Chairman and SEK 20,000 for each of the other members of the committee.

## *Chairman of the Board*

The Chairman of the Board is responsible for leading the work of the Board and for the Board to fulfill its obligations in accordance with the Companies Act and the Board's rules of procedure. Through continuous contacts with the CEO, the Chairman of the Board shall monitor the company's development and ensure that the Board receives the information required for the Board to fulfill its commitment. In addition, the Chairman, as a working Chairman of the Board, actively participates in financing issues, licensing issues and presentations to the market and assists company management in business development. Peter Rothschild has been Chairman of the Board since 2011.

## *The CEO*

The CEO is responsible for the company's business development and manages and coordinates day-to-day operations. The CEO has an instruction decided by the Board of Directors, which regulates, among other things, his work with management and development of the company as well as continuous reporting and decision-making to the Board. The Managing Director prepares the necessary information and decision-making documentation such as reports regarding, among other things, the company's finances, order situation, significant business and strategic issues before Board meetings, and is a rapporteur and submits motivated proposals for decisions. In addition, the President keeps the Chairman of the Board regularly informed about the company's operations.

The Managing Director is solely responsible for external communication.

The Board annually evaluates the CEO's work. In this evaluation no one from the company management is present.

## *Management*

The management of IBT consists of five people.

The management team is led by the CEO and is responsible for planning, directing and monitoring the day-to-day operations. Minuted meetings are held every week. The powers and responsibilities of the CEO, in addition to being regulated by the Companies

Act, are defined in the CEO instructions adopted by the Board. The powers and responsibilities of company management are defined in job descriptions and attestation instructions.

### *Remuneration Committee*

The Board has appointed a Remuneration Committee consisting of Chairman of the Board Peter Rothschild and Board member Anthon Jahreskog. The Remuneration Committee shall prepare questions regarding remuneration and other terms of employment for the President and other senior executives who together form the company management. Principles for remuneration to senior executives are set at the Annual General Meeting. The remuneration committee's task is to prepare proposals in accordance with these principles.

### *Auditors*

IBT's auditors are normally elected for a period of one year at the AGM. At the 2020 Annual General Meeting, a re-election of Deloitte AB was resolved for the period up to the end of the Annual General Meeting that will be held in 2021. The Auditing Company has appointed Birgitta Lööf as the Chief Auditor. Remuneration to the auditors is paid, in accordance with the decision of the Meeting, on an ongoing basis.

The auditors review the Board of Directors and the CEO's management of the company and the quality of the company's financial reporting. The auditors also carry out, on behalf of the Board, an audit of the financial statements, an audit of the annual report, and a review of a quarterly report.

The auditor's report their audit to the shareholders through the audit report, which is presented at the AGM. In addition, written and oral reports are submitted to the company management and the board. At the board meeting in connection with the review of the third quarter, the auditor participates in the reporting of comments from the ongoing review during the financial year regarding the company's internal control and preparation for the annual accounts.

The auditors also submit an audit opinion on the corporate governance report and a report on the review of remuneration to senior executives.

For information on remuneration to the auditors, see note 5 in the annual report.

The Board of Directors has decided that independent members of the Board possess accounting expertise as well as the Board's ongoing review of the financial reporting and with regard to the company's limited size and scope of transactions, to appoint no Audit Committee. Furthermore, the entire Board meets with the auditor at least once a year without the presence of the company's CEO or another of the company management.

## *The Board's description of internal control regarding the financial reporting for the financial year 2020*

### Introduction

According to the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance, the Board is responsible for the internal control. This description has been prepared in accordance with these provisions and thus limited to internal control over the financial reporting.

### Internal control over financial reporting

The Board of Directors is responsible for ensuring that the company's organization is designed so that the accounting, asset management and the company's financial conditions are otherwise controlled in a satisfactory manner.

The Board of Directors adopts an annual rules of procedure for the work of the Board and instructions for the division of work between the Board and the CEO. The rules of procedure specify which matters require the approval or confirmation of the board. At the board meetings, the CEO prefers matters that require the board's treatment.

The Managing Director shall ensure that the Board receives a factual, detailed and relevant information base for the Board to be able to make well-informed decisions and that the Board is kept regularly informed of the development of the company's operations and financial position.

Within IBT, internal control of financial reporting is focused, for example, on ensuring efficient and reliable management and accounting of purchases and sales, other income accounting and accounting of the company's financing. The internal control environment mainly comprises the following five components: control environment, risk assessment, control activities, information and communication and follow-up.

### Control environment

In addition to the rules of procedure between the Board and the CEO, IBT's control structure is based on the company's organization and ways of conducting operations where the roles and responsibilities are defined and communicated in the organization. Employee awareness of maintaining good control over financial reporting is satisfactory and analysis and follow-up of financial progress is done monthly. Financial reports and compilations are made by IBT's finance department and reported to the Board on a quarterly basis and to company management on a monthly basis.

### Risk assessment

The company works continuously with risk assessment and risk management to ensure that the risks to which the company is exposed are managed within the framework that is ultimately determined by the Board of Directors. The company management annually analyzes the business processes of the business with regard to efficiency and risks. This work includes identifying significant risks of errors in financial reporting and ensuring that there are appropriate processes and controls within the business to manage these risks. Processes that are considered to be of particular importance to IBT are research and development. A more detailed description of the risk exposure can be found in the annual report.

### Control activities

The risks identified in financial reporting are managed through a number of control measures in the business processes. Processes, policies and controls are reviewed and updated annually. The purpose is to detect, prevent and correct errors and deviations. The control structure also includes, among other things, established powers (eg attestation), division of work, IT risks and the management's monthly review of financial information. The company controls the subcontractor's fulfillment of current services in accordance with agreements, including quality aspects.

### Information and communication

IBT has information and communication pathways aimed at promoting completeness and accuracy in financial reporting. Certificate arrangements and communication policies are distributed to all employees and kept available on the company's intranet. The entire company's staff meet approx. once a month to increase knowledge of processes and objectives and to exchange information and experience.

### Evaluation

The company management annually evaluates internal control. The company's elected auditors, Deloitte AB, also annually review a selection of IBT's routines and internal controls. The Board then evaluates the information and ensures that measures are taken regarding the deficiencies and proposals that have emerged.

The company has no special internal audit function (internal audit). The Board has made the assessment that, given the company's size and scope of transactions, as well as the expertise in the area that the Board possesses and the Board's meeting with the auditor, there is no reason to establish a formal internal audit department.

## *SHARES*

On January 1, 2020 and December 31, 2020, respectively, the total number of shares amounted to 11 226 184 of which 377 736 class A-shares carrying ten votes and 10 848 448 class B-shares carrying one vote.

IBT's class B share was listed on Nasdaq Stockholm, Mid Cap, on September 10, 2018. The number of shareholders amounted to 5 898 on December 31, 2020 according to Euroclear Sweden compared to 5 593 on December 31, 2019.

### *Share price development*

IBT's share price decreased from 137 SEK to 112 SEK during 2020. The market value as of December 31, 2020 amounted to 1 215 MSEK.

### *Analysts covering IBT:*

SEB: Christopher W. Uhde, PhD

## Ownership December 31, 2020

Name	Series A-shares	Series B-shares	Share capital %	Voting rights %
ANNWALL & ROTHSCHILD INVESTMENTS AB	377 736	410 478	7.02	28.63
ÖHMAN BANK S.A.	-	1 174 017	10.46	8.03
FJÄRDE AP-FONDEN	-	1 112 919	9.91	7.61
SWEDBANK ROBUR NY TEKNIK BTI	-	579 172	5.16	3.96
AMF AKTIEFOND SMÅBOLAG	-	501 585	4.47	3.43
HANDELSBANKEN SVENSKA, SMABOLAGSFOND	-	450 675	4.01	3.08
TREDJE AP-FONDEN	-	438 565	3.91	3.00
CBNY-NORGES BANK	-	329 620	2.94	2.25
UNIONEN	-	322 196	2.87	2.20
DANGOOR, DAVID	-	278 421	2.48	1.90
Sub-total	377 736	5 597 648	53.23	64.09
Other shareholders	-	5 250 800	46.77	35.91
Total	377 736	10 848 448	100	100

Source: Euroclear Sweden

## MANAGEMENT

### *Staffan Strömberg*

CEO since 2013. Born 1967.

M.Sc. in chemical engineering and Ph.D. in organic chemistry from the Royal Institute of Technology in Stockholm.

Staffan Strömberg has more than 20 years of experience in the pharmaceutical industry. Besides his roles at Billerud Tenova Bioplastics and at the Swedish Medical Products Agency, he has also been Vice President of NlcOx France, had various project management positions in AstraZeneca and been Head of R&D of Swedish Orphan.

Member of the Board of Directors of Eteboxagu AB and BioGaia Pharma AB.

Former CEO of Billerud Tenova Bioplastics AB and Head of Medical Devices at the Swedish Medical Products Agency.

Shareholding in the Company: 41,728 series B shares and 70,000 warrants and 45,864 series B shares through the wholly owned company Eteboxagu AB.

### *Anders Kronström*

COO since 2018. Born 1967.

M.Sc., M.B.A.

Anders Kronström has over 20 years of experience working in the pharmaceutical industry. His experience spans across all stages of drug development in different disease segments. During his career at AstraZeneca he has had senior leadership positions within Project Management and Business Development. More recently, he was a CEO of Biosergen AS, a Norwegian biotechnology company.

Shareholding in the Company: 3 170 shares of series B and 50 000 warrants 2017/2022 and 40 000 warrants 2020/2024.

### *Eamonn Connolly*

Head of R&D since 2013. Born 1957.

Doctor of Philosophy (Ph.D.), University of Manchester Institute of Science and Technology and B.Sc. (Hons) Biochemistry, First class, University of Manchester.

Eamonn Connolly has more than 25 years of experience of the pharmaceutical and biotechnology industry from his various positions within companies such as: BioGaia, Fresenius Kabi and Pharmacia & Upjohn.

Previously member of the Board of Directors of IBT.

Shareholding in the Company: 56,864 series B shares and 50,000 warrants.

### *Daniel Mackey*

CFO since 2017. Born 1974.

Bachelor of Science in Economics, State University of New York, Plattsburgh, New York.

Daniel has 20 years of experience from management positions in finance from American and international companies such as Investors Bank & Trust Co, Nordea Investment Management AB and Nordea Bank AB.

Shareholding in the Company: 6,120 series B shares and 50,000 warrants 2017/2022 and 20 588 warrants 2020/2024.

### *Professor Jonas Rastad, MD, Ph.D.*

CHIEF MEDICAL OFFICER since 2019. Born 1950.

Jonas has in excess of 20 years of experience as academic surgeon and has published 250 articles in peer review-magazines. He has held several leading positions at AstraZeneca in Sweden, Japan, The UK and USA. In addition, he has 13 years of experience of public leadership positions, among other head of the Kalmar regional hospital, Västerbottens county council and CEO of Region Skåne.

Shareholding in the Company: None

## *BOARD OF DIRECTORS*

IBT's Board of Directors consists of five (seven) ordinary members, including the chairman of the board, with no deputy board members, all of whom are elected for the period up until the end of the annual shareholders' meeting 2020.

### *Peter Rothschild*

Chairman of the Board since 2011. Born 1950.

Master of Business Administration from Stockholm School of Economics.

Founder and Chairman of the Board of Directors of BioGaia AB, BioGaia Pharma AB and MetaboGen AB, and Annwall & Rothschild Investments AB. Board member of Allbright.

Previously CEO of BioGaia (publ) and member of the Board of Directors of Moberg Pharma AB (publ).

Shareholding in the Company: 377,736 series A shares and 410,478 series B shares through Annwall & Rothschild Investments AB, a company co-owned with Jan Annwall.



### *Margareta Hagman*

Board member since 2015. Born 1966.

Master of Business Administration, Orebro University.

Advisor and consultant in business, accounting and finance.

Previous positions: Deputy CEO and CFO of BioGaia AB (publ). Member of the Board of Directors of BioGaia Production AB and CapAble AB and Annwall & Rothschild Investments AB.

Shareholding in the Company: 3,570 series B shares.

### *Eva Idén*

Board member since 2017. Born 1966.

Civil engineer in chemistry, Chalmers tekniska högskola.

Chairman of the board of Better & Beyond AB.

Previously held management positions at AstraZeneca AB.

Shareholding in the company: 30 series B shares.

### *Anthon Jahreskog*

Board member since 2017. Born 1980.

Candidate degree in Management and systems, City University, London. Bachelor of business administration, Master of science in financial management at University of Cape Town.

Board member of BioGaia AB (publ) and Fast Track Holdings Ltd.

Until July, 2015 Chief Operating Officer, Fund Linked Products, Credit Suisse Investment bank, London. Anthon is a business strategy consultant in several industries.

Shareholding in the company: 1 000 series B shares.

### *Kristina Sjöblom Nygren*

Board member since 2018. Born 1961.

Kristina is a Doctor of Medical Sciences from the Karolinska Institute and a licenced physician.

She is since 2017 2017 Chief Medical Officer, Head of Development at Santhera Pharmaceuticals in Basel. Kristina Sjöblom Nygren has extensive experience from the pharmaceutical industry among other as Head of Clinical Development at SOBI.

Shareholding in the company: None

### *Robert Molander*

Board member since 2020. Born 1965.

Robert Molander has an MBA from Washington University in Marketing and Finance and two Bachelors degrees from Miami University in Economics and International Studies.

Robert is active as an advisor and consultant in commercial strategy, launch preparation, marketing and sales in the pharmaceutical industry. Previously sales and marketing Director at Trialbee AB. Robert has 25 years of experience in marketing and sales in the USA from pharmaceutical companies, among other Novartis, Pfizer and Pharmacia.

Shareholding in the company: 500 series B shares

### **Contact Persons**

Staffan Strömberg, CEO

Daniel Mackey, CFO

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### **Contact Information**

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